Massachusetts State Police

Forensic Services Group

Quality Manual
Version 21.0

TABLE OF CONTENTS

1.0 INTRODUCTION

This quality manual addresses requirements set forth by the American Society of Crime Lab Director/Laboratory Accreditation Board, which encompasses ISO/IEC 17025:2005 International Standards.

This Quality Manual is approved by the Deputy Division Commander of the Forensic Services Group, the Laboratory Director, and the Quality Manager.

1.1 MASSACHUSETTS STATE POLICE FORENSIC SERVICES GROUP MISSION STATEMENT

Excellence in Service through Quality Forensic Science.

1.2 MASSACHUSETTS STATE POLICE FORENSIC SERVICES GROUP QUALITY POLICY STATEMENT

The Massachusetts State Police Forensic Services Group (MSPFSG) is committed to providing the best quality service available to all members of the criminal justice community. To accomplish this, a quality system has been established by the MSPFSG to provide the criminal justice community with continuing confidence that laboratory results are forensically defensible.

It is imperative that all work conducted by the MSPFSG be of the highest quality possible. This applies not only to the actual technical laboratory work performed, but also to the written reports that are generated as well as the court room testimony provided by the analysts.

Technical competency can be achieved only by the combination of a number of components such as initial training; experience; supervision of casework; continuing education and professional development; proficiency testing; and an appreciation of the scientific procedure/methodology, all of which must be projected against a background of proper professional ethics. Each component is important and overlaps with the others. One cannot embrace one component of quality assurance and disregard the others. Quality assurance does not rest on a single component.

Quality assurance is a dynamic endeavor, all encompassing and never-ending.

All personnel within the laboratory are required to familiarize themselves with the quality assurance documentation and implement these policies and procedures in their work.

1.3 MSPFSG GOALS AND OBJECTIVES

The following objectives of the Quality System are supported and understood by the staff of the MSPFSG:

- To ensure scientifically sound technical methods and procedures utilizing appropriate instruments and equipment
- To provide results that are traceable and accurate while pertinent to the needs of the criminal justice community.
- To provide relevant, competent and impartial testimony in judicial proceedings.
- To provide continuing education and support to all analysts through a professional development program.
- To demonstrate through documentation that quality control procedures are, in fact, being conducted.
- To provide a foundation for meeting and maintaining all requirements for laboratory accreditation.

2.0 SCOPE OF SERVICES

This manual applies to the following ASCLD/LAB MSPFSG locations:

Boston
Bourne
Danvers
Devens
Lakeville
Maynard (Central Laboratory)
North Sudbury
Springfield
Sudbury

The drug testing laboratory in Amherst is currently not accredited nor bound by this QA manual.

The MSPFSG carries out validated forensic analyses in the following categories:

Biology
Breath Alcohol Testing

Controlled Substances
Crime Scene Response
Digital Evidence
Firearms Examinations
Impression Evidence
Toxicology
Trace Evidence

3.0 DEFINITIONS, ABBREVIATIONS, AND REFERENCES (as applicable to MSPFSG)

3.1 DEFINITIONS

Accreditation Cycle: The period of time between accreditation dates, generally 5 years.

Accountability: The quality of subordinate workers acting responsibly in performing their work and answerable to a superior.

Adequate: The principle of being sufficient for a specific requirement.

Administrative documentation: Records such as case-related conversations, evidence receipts, police reports, case jackets, and other pertinent information. Does not include technical records.

Administrative review: Review of case records for consistency with laboratory administrative policies and for editorial correctness.

Analyst: An individual who conducts and/or directs the analysis of forensic casework samples, interprets data, reaches conclusions, and issues reports concerning conclusions.

Approved Test Provider: A proficiency test provider which has complied with the test manufacturing guidelines and requirements established by ASCLD/LAB and have been recognized.

Association: A relationship which is concluded to exist between individuals and/or objects based upon examination/analysis.

Audit: A review conducted to compare the various aspects of the laboratory's performance with a standard for that performance.

Blank: Test conducted with a reagent in the absence of a standard or sample.

Blind sample: A proficiency test sample, for which the analyst is unaware of the test nature of the sample at the time of analysis.

Case file/envelope: See case record.

Case Management Section: A section within the MSPFSG that assists with case assignments and coordination, liaison duties between various agencies throughout the Commonwealth and the MSPFSG.

Case record: Files (and/or envelopes) and electronic information pertaining to a particular case that contain administrative and examination documentation generated and/or received by the laboratory.

Calibrate: To standardize by determining the deviation from a standard to ascertain the proper correction factors.

Chief Science Officer: See Laboratory Director.

Competency test: The practical, oral or written evaluation of a person's ability to perform work in any functional area prior to the performance of independent casework.

Commander of Forensic Services: See Deputy Director

Control: Test performed in parallel with experimental samples and designed to demonstrate that a procedure/chemical is working correctly.

Corrected report: A report issued from the laboratory that corrects erroneous information previously reported.

Corrective action: The process by which a deficiency is brought into conformity with a standard.

Crime scene: A location external to a laboratory facility where evidence is identified, documented, collected, and/or interpreted.

Critical reagent: Reagents such as commercial supplies and kits whose nature is essential to obtaining an accurate test result.

Customer: A person or organization who requests services from the laboratory.

Deficiency: An inadequacy; lacking in some necessary quality of an element, including missing data, incomplete data, or incomplete reports.

Deputy Director(s): Individual with authority to manage and/or oversee the Forensic Biology, Forensic Chemistry, Forensic Support, and/or Forensic Services Sections of the MSPFSG as assigned by the Laboratory Director.

Deputy Division Commander of Forensic Services Group: The sworn member of the Massachusetts Department of State Police who oversees all MSPFSG administrative operations.

Digital Evidence: Evidence stored or transmitted in binary form.

Director: See Laboratory Director.

Director of Administrative Services: Oversees administrative staff and, under the direction of the Laboratory Director, the financial functions of the FSG.

Discipline: A major area of casework for which a laboratory may seek accreditation.

Discrepancy: Being variant or different from the accepted consensus.

DNA Technical Leader: An individual who has the overall responsibility of the technical operations in the DNA Unit, per the FBI Quality Assurance Standards.(Also see Section Supervisor)

Document: A piece of written, printed, or electronic matter that provides information or evidence or that serves as an official record.

Drug Chemistry: The analysis of controlled substances either in pure, legal, or illicit dosage forms.

Evidence: Material, regardless of form, which is received by a laboratory for the purpose of obtaining information relevant to a criminal investigation.

Examination documentation: Includes reference to tests conducted, standards and controls used, diagrams, printouts, notes, observations and results of examinations (also examination record).

Expert Testimony: Testimony about a scientific, technical, or professional issue given by a person qualified to testify because of familiarity with the subject or special training in the field.

External proficiency: A test program managed and/or controlled independent of the laboratory system.

Facility Security Administrator: The Facility Security Administrator ensures that all security related functions are properly executed and followed

Firearms Examination: Examination and/or comparison of evidence resulting from discharge and/or use of firearms.

Forensic Biology: Refers to Arson and Explosives, Crime Scene Response, Criminalistics, DNA, and Trace.

Forensic Chemistry: Refers to Drugs, Office of Alcohol Testing, and Toxicology.

Forensic Services: Refers to CODIS Investigation Unit, Crime Scene Services, Digital Evidence, and Firearms Identification.

Forensic Support Sections: Refers to Case Management Unit and Evidence Control Unit

Form: A document with blanks for the insertion of details or information.

Health and Safety Coordinator: The person designated by the Laboratory Director to have the responsibility of overseeing the safety program within the MSPFSG.

Inconsistency: Any reported results that differ from the consensus results. Inconsistencies may be classified as administrative, systemic, analytical or interpretive.

Internal proficiency: Proficiency testing program managed and controlled within the laboratory system.

Known sample: A specimen of an identified source acquired for the purpose of comparison with an evidence sample; synonymous with exemplar.

Laboratory Director: This individual has the authority to manage and oversee all aspects of the Forensic Services Group.

Latent Prints: Development and/or comparison of latent print impressions.

Laboratory Information Management System (LIMS): Laboratory Information Management System (LIMS) is a software system used in forensic laboratories for the management of evidence, samples, laboratory users, instruments, standards and other laboratory functions. The system provides an efficient way to enter, store, and retrieve case-related information and is the primary means by which the tracking of evidence is achieved.

Lead Supervisor: See Section Supervisor

Memorandum: A written proposal or brief record outlining an update to an existing document to be immediately implemented, prior to its incorporation into that document.

Method: The course of action or technique followed in conducting a specific analysis or comparison leading to an analytical result.

Natural Science: A branch of science that deals with the physical world, e.g. physics, chemistry, geology, and biology.

Notes: The documentation of procedures, standards, controls and instruments used, observations made, results of tests performed, charts, graphs, photos, and other documents generated and used to support the examiner's conclusions.

Objective: A measurable, definable accomplishment which furthers the goals of the organization.

Organizing: The process of identifying, specifying and assigning work, grouping work and resources into a structure, and establishing a chain of command between individuals and groups.

Planning: The analysis of relevant information from the present and past and the assessment of probable future developments so that a course of action may be determined that enables the organization to meet its stated objectives.

Policy: A guiding principle, operating practice, or plan of action governing decisions made on behalf of an organization.

Principle: A basic rule, assumption or quality; a fixed or predetermined policy or mode of action.

Procedure: A directive listing the actions or activities to be followed in performing a particular laboratory examination or operation; the overall plan for analysis of a particular item of evidence.

Proficiency Tests: Tests to evaluate the competency of analysts, technical support personnel, and the quality performance of a laboratory.

Proficiency Test Grader: An individual assigned by Quality Assurance in consultation with the Section Manager to aid in the evaluation of proficiency test results. The proficiency test grader must be or have been a qualified technical reviewer in the applicable discipline.

Quality Assurance: The planned and systematic actions necessary to provide sufficient confidence that a laboratory's product or service will satisfy given requirements/standards for quality.

Quality Audit: A management tool used to evaluate and confirm activities related to quality. Its primary purpose is to verify compliance with the operational requirements of the quality system.

Quality Control: Activities designed according to established standards that are used to ensure the quality of analytical data and that it satisfies specified criteria.

Quality Management System Program (QMS): Customized computer program that provides document control, version management and designated task assignments within the laboratory's management system.

Quality Assurance Manager: An individual designated by the Laboratory Director who, irrespective of other responsibilities, has the defined authority and obligation to ensure that the requirements of the quality system are implemented and maintained, and is responsible for ensuring compliance with the ASCLD/LAB standards.

Quality Manual: A document stating the quality policy and describing the various elements of the quality system and quality practices of the organization.

Quality Management System: The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management; includes all activities which contribute to quality, directly or indirectly. Equivalent to a management system described in ISO 17025, Section 1.4.

Questioned Sample: An evidence sample examined for the purpose of comparison or

identification.

Reagent: A substance used because of its chemical or biological activity.

Reference standard: A sample (with known properties) that is acquired or prepared for calibrating equipment and/or for use as a control in experiments.

Reliability: The quality of being dependable (may refer to personnel, materials or equipment).

Safety Manual: A document stating the safety policy and describing the various elements of the safety system of the organization.

Section: An area within the MSPFSG where specific duties occur. MSPFSG Sections include Administration, Biology, Case Management, Chemistry, Crime Scene Services, Digital Evidence, Firearms, and Forensic Support.

Section Commander: See Section Manager.

Section Manager: (Refers to the Manager of Biology and/or Chemistry, and the Section Commanders of Digital Evidence, Firearms Identification Section, Crime Scene Services) An individual who has the overall responsibility of the technical operations in a Section.

Section Supervisor: An individual who has the overall responsibility of the technical and personnel operations in a Section. (In DNA also referred to as Technical Leader).

Standard Operating Procedure: An established or prescribed method that is routinely followed for the performance of designated operations or in designated situations.

Sub-discipline: A specific type of analysis within an accredited discipline.

Technical Leader: See Section Supervisor

Technical Leader for DNA: See Section Supervisor

Technical procedures: Of or relating to a practical subject organized on scientific principles.

Technical review: The review of notes, data, and other documents, which form the basis for a scientific conclusion.

Technical Reviewer: An individual having expertise in a specific discipline gained through documented training and expertise.

Testimony: The firsthand authentication of a fact.

Toxicology: Analysis of biological materials for the presence of alcohol, drugs, and other substances.

Trace Evidence: The physical and/or chemical examination/analysis of materials, frequently found in limited or trace quantities. Many categories of testing, which are not specifically listed under other disciplines, may be included in the Trace Evidence Discipline.

Unit: Smaller division of a Section which performs specific duties. Units include Bomb and Arson/Trace, Drugs, Toxicology, Office of Alcohol Testing, Criminalistics, Crime Scene Response, DNA, CODIS Collection and Investigation, Evidence Control.

Unit Supervisor: An individual who is responsible for day to day operations in a Unit.

Validation: The process of performing a set of experiments that establish the efficacy and reliability of an instrument/method or procedure or modification thereof.

Verification: The act of another qualified examiner interpreting data and reaching the same conclusions as the reporting analyst.

3.2 ABBREVIATIONS (commonly used within the MSPFSG)**:**

ADA: Assistant District Attorney

ADMIN: Administration Unit

ASCLD/LAB: American Society of Crime Lab Directors/Laboratory Accreditation Board

CAR: Corrective Action

CCIU: CODIS Collection and Investigative Unit

CFU: Computer Forensics Unit (now referred to as DEMS)

CMU: Case Management Unit

CoA: Certificate of Analysis

CODIS: Combined DNA Index System

CRIM: Criminalistics Unit

CSRU: Crime Scene Response Unit

CSSS: Crime Scene Services Section

CV: Curriculum Vitae

DA: District Attorney

DEMS: Digital Evidence and Multimedia Section

DIS: Division of Investigative Services

ECU: Evidence Control Unit

EOPSS: Executive Office of Public Safety and Security

FIS: Firearms Identification Section

FSG: Forensic Services Group

IHP: In house profile (DNA)

ISO/IEC: International Organization for Standardization/International Electrotechnical Commission

LIMS: Laboratory Information Management System

MFR: Memorandum for Record

MSDS: Material Safety Data Sheet

MSP: Massachusetts State Police

MSPFSG: Massachusetts State Police Forensic Services Group

NIST: National Institute of Standards and Technology

OAT: Office of Alcohol Testing

OTIS: Office of Technology and Information Systems

PRC: Proficiency Review Committee

PT: Proficiency Test

QA: Quality Assurance

QAS: Quality Assurance Standards (FBI)

QAMS: Quality Assurance Management Section

QMS: Quality Management System Program

STR: Short Tandem Repeat

TOX: Toxicology Unit

Y-STR: Short Tandem Repeat on the Y Chromosome (male specific)

3.3 REFERENCES:

- ASCLD/LAB-*International,* ASCLD/LAB Policy on Traceability of Measurement Results, Reference Standards and Reference Materials; AL-PD-3050 Ver. 1.0, 2011.
- ASCLD/LAB-*International*, ASCLD/LAB Guidance on Traceability of Measurement Results, Reference Standards and Reference Materials; AL-PD-3054 Ver. 1.0, 2011
- ASCLD/LAB-*International*, ASCLD/LAB Policy of Measurement Uncertainty; AL-PD-3050 Ver. 1.0, 2011.
- ASCLD/LAB-*International*, ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty – Overview; AL-PD-3055 Ver. 1.0, 2011
- ASCLD/LAB-*International*, ASCLD/LAB Policy on Sampling, Sampling Plans, and Sample Selection in the Drug Chemistry Discipline; AL-PD-1018-Ver 2.0, 2011.
- ASCLD/LAB-*International*, ASCLD/LAB Guidance Document on Sampling, Sampling Plans and Sample Selection; AL-PD-3053-Ver 2.0
- ASCLD/LAB-*International*, Program Overview, 2010 Edition; AL-PD-3041-Ver 2.0, 2010.
- ASCLD/LAB-*International*, ASCLD/LAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists; AL-PD-1014-Ver1.1, 2011
- ISO/IEC 17025 International Standard– General requirements for the competence of testing and calibration laboratories; ISO/IEC 17025:2005(E).
- ISO 9000 – Quality Management Systems – Fundamentals and vocabulary, 3rd Edition; ISO 9000:2005(E).
- FBI, Quality Assurance Standards for Forensic DNA Testing Laboratories, 2011.
- FBI, Quality Assurance Standards for DNA Databasing Laboratories, 2011.
- ASCLD Code of Ethics
- ASCLD/LAB-*International*, Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories, 2011 Edition; AL-PD-3040-Ver1.2, 2010
- Massachusetts Department of State Police General Orders

4.0 MANAGEMENT

4.1 MANAGEMENT ORGANIZATION

The responsibilities, authority, and interrelationships of personnel within the MSPFSG are shown within the Organizational Chart.

4.1.1
The Massachusetts State Police Forensic Services Group is part of the Massachusetts Department of State Police. The MSPFSG consists of both sworn and civilian members of the agency. The Organizational Chart reflecting the management structure of the Laboratory is attached as QAMS-D002 to this Manual. Top and key management positions are designated on the organizational chart.

Refer to MSPFSG Organizational Chart

4.1.1.1 Commander of the Forensic Services Group
The Commander of the Forensic Services Group is a member of the MSP Command Staff that is responsible for the administrative and operational duties within the Forensic Services Group.

4.1.1.2 Laboratory Director
The Laboratory Director, under the administrative direction of the Commander of the Forensic Services Group, shall have the authority and responsibility to manage and oversee all aspects of the Forensic Services Group.

4.1.1.3 Deputy Director(s)
Individual with authority to manage and oversee the Forensic Biology and/or Forensic Chemistry and/or Forensic Support and/or Forensic Services Sections as assigned by the Laboratory Director.

4.1.1.4 Director of Administrative Services
Individual with authority to manage and oversee the Administrative Unit of the Forensic Services Group. Under the direction of the Laboratory Director, this individual manages and oversees the financial functions of the Forensic Services Group.

4.1.1.5 Quality Assurance Manager
The Quality Assurance Manager is responsible for ensuring that the management system, as it relates to quality, is implemented and followed at all times, as well as ensuring compliance with the International Standard (ISO/IEC 17025:2005 (E)). S/he is also responsible for developing, preparing and maintaining laboratory policies, including their dissemination and document control. The Quality Assurance Manager reports directly to the Laboratory Director and works with all members of the Management Staff to improve the quality system.

4.1.1.6 Section Managers
A Section Manager manages work under the direction of a Deputy Director, developing operational strategies and determining budgetary needs for the section. Additionally, Section Managers monitor section metrics on a regular basis, continually evaluate the section for quality and efficiency enhancements.

4.1.1.7 Section Supervisors
A Section Supervisor oversees casework examinations and analyses and maintains technical expertise in the respective sections. In applicable sections they may be referred to as Technical Leaders. Under the direction of the Section Manager, Section Supervisors establish procedures and methods; monitor the daily operations, budgetary requirements of the section; and activities of personnel engaged in performing physical, digital, chemical, biological and physical tests.

4.1.1.8 Unit Supervisors
A Unit Supervisor is a first line supervisor that is responsible for the daily operations and analyst assignments at the Unit level. A Unit Supervisor may conduct as well as supervise physical, digital, chemical and/or biological laboratory methods, or on-site examinations at crime scenes, in order to provide forensic assistance to investigators, attorneys and other clients of the Forensic Services Group.

4.1.1.9 Health and Safety Coordinator
The laboratory will have a person designated as the Health and Safety Coordinator, who will have the responsibility of overseeing the overall safety program within the MSPFSG. This will include reviewing and revising the Safety Manual each year, providing employees with safety awareness training, and conducting safety meetings as necessary. This person is responsible for ensuring that the health and safety program is implemented and followed at all times.

4.1.1.10 Staff and Management
Staff members are responsible for compliance with the MSPFSG Policies and ASCLD/LAB-International Standards as they apply to their discipline. It is expected that, due to the nature of forensic science, staff will use their education, training, experience, good judgment, and ethical obligation to provide quality forensic services. Staff will work with Management to support all aspects of the Quality Assurance Program. This includes:

- Promoting an efficient and effective operation within the MSPFSG.
- Assisting staff of the laboratory to perform their assigned duties and tasks; and
- Ensuring that the final product generated by the laboratory is of the highest quality possible while meeting the needs of the criminal justice community.

Communication through all Sections of the MSPFSG is essential. Regular communication through all channels and between staff members is strongly encouraged.

4.1.2 Staff Meetings

The Laboratory Director establishes a proper flow and pattern of communication throughout the MSPFSG so that all have input into the system. Regularly held staff meetings are good tools for maintaining open communication between laboratory personnel, which is essential for effective operations. The MSPFSG encourages frequent staff meetings within each Section and between Sections as needed. Direct communication on any technical matters within the laboratory, sub-laboratories, and individual examiners is encouraged.

The minutes of staff group meetings will be maintained by each Section, and shall be made available to all staff members for review. Section supervisors will provide these minutes to Quality Assurance when requested.

The most senior staff member (or designee) attending the meeting will be responsible for ensuring that the minutes are written, reviewed, and approved. Section supervisors are responsible for ensuring that any absent employee review the minutes as necessary.

4.2 MANAGEMENT SYSTEM

The management system at the MSPFSG documents the policies and procedures to be followed in order to ensure that the laboratory is providing services of the highest quality. The Management system consists of the Quality Manual, as well as Section procedures. The documents of the MSPFSG Management system are available to all staff electronically.

4.3 DOCUMENT CONTROL

Laboratory Personnel shall refer to all MSPFSG Procedures as well as applicable Massachusetts Department of State Police laboratory policies and procedures when performing their job duties.

It is the responsibility of the Director, Deputy Directors, Section Managers, Section Supervisors, DNA Technical Leader, CODIS Administrator, Health and Safety Coordinator, and Quality Assurance Manager to identify all documents of external origin that have an impact on the quality management system.

It is the responsibility of the Division Commanders and Laboratory Director to identify all Department of State Police documents of external origin that pertain to policy and procedure that affect MSPFSG operations.

Documentation may be in any form of media, including but not limited to electronic, hard copy, digital, written, or photographic. Any strikethroughs or carets on a document must be initialed and dated.

4.3.1 Document Control Policy

The Quality Assurance Manager or designee is responsible for developing, preparing and maintaining all controlled copies of authorized policies, which will be maintained electronically and be accessible to all staff. The Quality Assurance Section is responsible for posting the approved policies electronically and notifying employees when policies are approved.

The controlled copy of a document will be stored electronically. Any other copy, including printed or electronic, is not considered controlled and when printed shall say "Uncontrolled Copy".

Forms are considered controlled documents. They will not say "uncontrolled document" when printed out for use.

Memos are considered controlled documents.

It is the responsibility of the Section Supervisors to ensure that only current, approved policies are in circulation if they are printed and kept in each Section. When individual analysts print out uncontrolled copies of the policies and/or procedures, it is the individual's responsibility to replace those documents when they are made aware that there is a new version.

Upon written request from an authorized recipient, uncontrolled copies of policies may be released, with the approval of the Quality Assurance Manager.

4.3.2 Issuing Authority

Procedures:	The Laboratory Director is responsible for approving and issuing all procedures, after review by QAMS. The Health and Safety Coordinator may issue building specific safety instructions.
Forms:	The Deputy Director or Section Manager is responsible for issuing all forms for their respective Sections, after review by QAMS.
Memorandum:	The Section Manager is responsible for issuing all memos for their respective Sections and notifying QAMS when they are issued.

4.3.3 Archived Policies

QAMS archives policies that are no longer in effect. They are clearly identified as "archived" policies and removed from the current electronic policy list.

4.3.4 Master Document List

QAMS maintains the electronic master list of controlled documents. A copy of the master list is available electronically as a "read only" ~~document.~~form. When this list is updated, ~~the previous list will be archived offline with other archived documents/forms/memos. s.~~ The listit will clearly indicate current and obsolete documents, issue date, and revision numbers, ~~and substantive changes that were made to the document~~ The list will be archived annually, revising the list to contain only current

Comment [I1]: Might still want to have separate tabs for each section, just to make the flow easier for the analysts.

Formatted: Font color: Black, Highlight

Formatted: Indent: Left: 0.5"

information based on the annual ~~document~~ policy review done by each section/unit. As the list is updated throughout the current year, it will still clearly indicate when a document has become obsolete.

Comment [I2]: Idea on how to keep the document under control. Please reword if necessary.

4.3.5 Document Identification

New and revised documents, forms, and memos are uniquely identified, dated, numbered, paginated and authorized. Each controlled document should contain the following information:

- Agency Name
- Document Name
- Document Number (memos do not require a version number)
- Issuing Authority
- Issue Date
- Page Numbers with Total Number of Pages
- Revision History (procedures only)

4.3.6 Document Numbering

The controlled documents will be numbered according to the following structure:

0-099	Technical Procedures
100-199	Training
200-299	Quality Control
300-399	Administrative
400-499	Evidence and Chain of Custody
500-599	Crime Scene Response Policies and Procedures

Series D600 and higher will be assigned according to the Section's discretion.

The Section/Unit designations will be as follows:

Administration=ADM
Arson=ARSN
Case Management Unit=CMU
CODIS Collection and Investigation=CCIU
Crime Scene Response=CSRU
Crime Scene Services Section=CSSS
Criminalistics=CRIM
Digital Evidence=DEMS
DNA=DNA
Drug Identification Unit=DRUG
Evidence Control Section=ECU
Firearm Identification Section=FIS

Forensic Services Group=FSG
Office of Alcohol Testing=OAT
Quality Assurance=QAMS
Safety=SAFE
Toxicology=TOX
Trace Analysis Unit=TRAC

The documents would be numbered as follows (examples):

- DRUG-D001-v.01.0, reflecting Drug Section, Document number one, version one.
- CRIM-D500-v.01.0, reflecting a Criminalistics Document relating specifically to a procedure for Crime Scene Response.
- TRAC-F300-v.01.0, reflecting an administrative form used by the Trace Section
- FIS-M101-v.1.0, reflecting a memo issued by the FIS Section.

Note: DNA Unit has a unique numbering system for memos issued within the Unit, as defined by their own procedure.

4.3.7 New Procedures:

Upon creating a new procedure, the following steps must be taken:

- After review and approval through the appropriate supervisory chain, the Section Manager forwards the Word document to QAMS for formatting and review.
- QAMS provides the document to the Laboratory Director for review and approval.
- The Laboratory Director will return the document to QAMS if changes are needed.
- Once there are no changes needed, the Director will sign on the signature page of the document and return it to QAMS.
- Staff will be notified electronically by QAMS when a new policy is issued.
- QAMS updates the electronic master list.

4.3.8 Revised Procedures

When revising a procedure, the following steps must be taken:

- The Section Manager, or designee will request the current policy from QAMS and s/he will make changes as needed to the policy using the "Track Changes" feature in Microsoft Word.
- After review and approval through the appropriate supervisory chain, the Section Manager forwards the Word document (with changes tracked), including any supporting documentation that may be needed (e.g. validation studies), to QAMS for formatting and review.

- QAMS provides the document(s) to the Laboratory Director for review and approval.
- The Director will return the document(s) to QAMS if changes are needed.
- Once there are no changes needed, the Director will sign on the signature page of the document and return to QAMS.
- Staff will be notified electronically by QAMS when a policy revision is approved.
- QAMS updates the electronic master list.

4.3.9 Annual Policy Review:
At a minimum, all policies are reviewed annually (by December 1st) by the appropriate Section Manager. This review should be conducted no less than 4 months apart and no more than 18 months apart. Documentation of this review will be forwarded to QAMS by the Section Manager.

4.3.10 Memorandum
Any amendments to policies which are made by memo, prior to the issue of the revised policy, will be clearly marked, initialed and dated.

Substantive changes are made as needed and may include:

- incorporating newly validated techniques
- archiving outdated techniques
- changes in methods
- changes in accreditation standards

On occasion, it may be necessary to publish interim or supplemental policy or memoranda. All interim policies and memos must be forwarded to QAMS, and subsequently incorporated into the appropriate procedure within 60 working days.

Formatted: Indent: Left: 0.17", Hanging: 0.33"

4.3.11 Employee Responsibility
All laboratory employees are required to read and comply with current laboratory and section policies. All employees are encouraged to participate in the on-going development and revision of policies by suggesting appropriate changes through the proper channels as outlined in the organizational chart.

4.4 REVIEW OF REQUESTS, TENDERS, AND CONTRACTS

The MSPFSG will clearly communicate to its customers the type of analysis that it uses. Additionally, the laboratory will ensure that the needs of the customer are clearly defined, documented, and understood by staff in order to select the appropriate methods. The laboratory will also ensure the protection of the customers' confidential information.

When evidence is received for analysis, this constitutes a contract with the customer. The terms

will be expressed on the evidence submittal form.

A signature on the submission form is indication that the customer agrees with the MSPFSG procedures for analysis.

If the MSPFSG is unable to meet the needs of the customer, this will be communicated to the them when the case is evaluated for examination. The analyst will notify the submitting agency and documentation of this notification will be retained in the case record.

Any communications with the customer that are pertinent to the testing of the evidence submitted, or the review of the request, including significant changes, shall be documented in the case record.

Note: MSPFSG will not conduct re-examination on evidence that has previously been examined. This does not apply if the type of analysis is something that was not originally performed on the evidence by the previous lab. Exceptions to this must be authorized by the Laboratory Director.
Note: OUI Samples that are being testing by an external lab must be retested in house within 72 hours of providing the sample to the external party.

4.5 SUBCONTRACTING OF TESTS

In order to provide the highest quality service possible, the MSPFSG may choose to transfer the evidence to another laboratory to perform the work. When the MSPFSG subcontracts work, this must be clearly communicated and, when appropriate, agreed to by the customer.

The customer must be notified, in writing, that the items submitted may be subcontracted to an outside agency. This work shall be placed with a contractor competent to perform the applicable type of testing. The contractor will be accredited by ASCLD/LAB or FQS. QAMS will maintain a list of the subcontractors used by the MSPFSG along with the supporting documentation ensuring their competency.

The MSPFSG maintains responsibility for any subcontracted work, unless the customer or other regulatory agency specifies which subcontractor will be used. In this instance, it will NOT be considered subcontracting.

Results obtained by a subcontractor shall be clearly communicated as such on laboratory reports.

Note: The DNA Unit has its own procedures, in accordance with Standard 17 of the QAS document, addressing DNA analysis performed by subcontracted/vendor laboratories.

4.6 PURCHASING AND SUPPLIES

Critical reagents, supplies, and services which affect the quality of testing will be obtained from reliable suppliers.

The Director of Administrative Services is responsible for ensuring that all staff is notified and

aware of how to obtain supplies and services, in accordance with applicable Department of State Police and Commonwealth of Massachusetts procedures. Specific Unit procedures outline the requirements for inspecting and ensuring quality control checks are completed prior to use when deemed necessary.

Please refer to the Massachusetts State Police Forensic Services Group Protocol for the Purchasing of Goods, Services, Inventory and Grants.

4.7 SERVICE TO THE CUSTOMER

4.7.1 Scope of Services

The laboratory offers investigative and crime scene support, forensic analyses and subsequent expert testimony on legal matters. These services to Local, State and Federal Law Enforcement agencies are provided by the Laboratory System's Headquarters Laboratory in Maynard and its satellite laboratories located in Boston, Bourne, Danvers, Devens, Lakeville, North Sudbury, Springfield, and Sudbury.

Each Section of the laboratory is committed to conducting impartial and objective examinations using the best available tools, and in accordance with ASCLD/LAB Accreditation and procedures.

The following types of examinations are currently offered by the MSPFSG:

4.7.1.1 Chemistry

The MSPFSG analyzes samples to identify controlled and non-controlled drugs and other substances. Other services include analyzing blood, urine, and other specimens for the presence of drugs, alcohol, and poisons. Additionally, analysis of items for the presence/absence of lachrymators is also performed.

4.7.1.2 Biology

The MSPFSG analyzes evidentiary samples for the identification of biological fluids. DNA analysis is performed on biological samples to determine if a viable DNA profile can be obtained and, when available and appropriate, those profiles are compared to known standards. Evidence is evaluated to determine items with the most probative value to an investigation. Suitable profiles are entered into CODIS. Bloodstain Pattern Analysis is also performed when necessary.

4.7.1.3 Physical Evidence

The MSPFSG performs examinations on physical evidence including but not limited to glass, fibers, hairs, paints, and bank dyes. Serial Number Restorations are performed, as well as the examination of automotive lamps to determine if they were on/off at the time of impact. Physical match examinations are performed. Additionally, weapons, clothing, sexual assault (RSA) kits and other items are examined for trace and biological

evidence. Gunshot Distance Determination is conducted. MSPFSG also performs analysis of fire debris, gunshot residue and explosive samples.

4.7.1.4 Crime Scene Examinations
Analysts respond to crime scenes which include homicides, reported sexual assaults, automobile accidents, and clandestine drug laboratories. The Crime Scene Responders are responsible for consultation and/or on-site technical assistance to law -enforcement personnel and officials at various types of scenes. The analysts are trained to recognize, document, test, collect, transport, analyze, interpret, and testify to the significance of physical and biological evidence.

4.7.1.5 Firearms
The MSPFSG performs examinations which include the identification and comparison of bullets, cartridge casings and shot shells to determine if they have been fired from a specific gun. Additional functions performed include weapon function and the use of the National Integrated Ballistics Information Network (NIBIN).

4.7.1.6 Impression Evidence
The MSPFSG analyzes evidence related to the development and recovery of latent print and other imprint/impression evidence. Comparison of friction ridge skin evidence (fingerprints, palm prints, footprints) is done, along with comparison of footwear, tire track and other imprint/impression evidence.

4.7.1.7 Digital Evidence and Multimedia Section (DEMS)
The MSPFSG supports investigations involving crime and computer technology. DEMS performs computer forensic examinations for state and local law enforcement. In addition, DEMS is dedicated to supporting investigations conducted by Internet Crimes Against Children (ICAC) task forces. DEMS also provides training to law enforcement officials concerning the proper seizure, storage, and analysis of digital devices.

4.7.1.8 CODIS Collection and Investigative Unit
This Unit qualifies and collects samples from offenders for entry into the CODIS database.

4.7.1.9 Breath Analysis Testing Program
The Office of Alcohol Testing (OAT) oversees the breath testing program for the Commonwealth of Massachusetts. They establish and maintain lists of approved breath testing devices in accordance with the Massachusetts General Laws and the National Highway Traffic Safety Administrations list of conforming products. The OAT also certifies annually all breath testing equipment used in Massachusetts, approves and distributes calibration standards used with breath testing devices, and establishes the standards for training and certification relative to breath testing.

4.7.2 Customer Feedback
The MSPFSG will routinely solicit feedback from its customers to identify potential areas for improvement, within both the Management System and in the testing procedures and reporting. These customers will include law enforcement agencies, attorneys, and others

who utilize services provided at the lab.

4.7.2.1 General Feedback

There are different ways that the MSPFSG will move to receive feedback from the customers on services provided.

Survey: Each MSPFSG facility will have hardcopies of the current survey available at the Evidence Control Unit window. The customer may fill out this survey and leave it with the Evidence Unit Personnel, or s/he may take it and mail/fax it back to the MSPFSG Quality Assurance Section.

The survey is also available on the Mass.gov website at http://www.mass.gov/eopss/law-enforce-and-cj/criminal-investig/crime-lab/

Formatted: Indent: Left: 1.5"

Annually, the Quality Assurance Section will solicit feedback from the District Attorney's Offices, and other customers as needed. This may be in the form of a survey or thru direct communication.

Electronically: A customer may communicate electronically with staff member(s) with his/her feedback, via email. The staff member will forward this information to the Quality Assurance Manager who will maintain it.

Directly: A customer may communicate via phone with staff member(s) with his/her feedback. The staff member will forward this in the form of an email to the Quality Assurance Manager who will maintain it.

Suggestion Box: There will be a suggestion box available in each facility, where both staff members and/or customers may communicate feedback.

Testimony Review: The MSPFSG uses a Testimony Review form to obtain feedback from courtroom testimony. An analyst may request a customer fill this out, or the customer may do so upon their own initiation. These forms are available as part of the QA Manual, or they may be requested from QAMS.

Feedback will be used and analyzed by the Quality Assurance Manager as necessary in the following manner:

- Suggestions for improvement will be forwarded to the Laboratory Director for consideration
- Surveys and other documentation with feedback will be forwarded to the Laboratory Director for discussion during the Management Review to identify trends which indicate further opportunity for improvement.

4.8 COMPLAINTS

Complaints may highlight areas for improvement within the MSPFSG and the Quality System, and should be dealt with appropriately.

The MSPFSG will adequately record and process complaints of a technical or administrative nature, in compliance with the Department of State Police General Order ADM-14. Any issues related to human resources or personnel in nature should be immediately brought to the attention of the employees' supervisor.

Add Coverdell Complaints info?? Or as an external document/statement

4.9 CONTROL OF NONCONFORMING TESTING

Nonconforming work will be identified when any aspect of examination, calibration, or results does not conform to procedures or meet the agreed needs of the customer. This procedure applies to all work that impacts the accuracy of results and the integrity of evidence.

It is the responsibility of all employees of the MSPFSG to report observations of non-conforming work. It can be discovered through management reviews, technical and administrative reviews, audits, complaints, quality checks, or other means.

The Deputy Director, Section Manager, and/or DNA Technical Leader have the authority to immediately suspend and/or subsequently resume any nonconforming work activity that could result in erroneous reports or testing data. S/he will notify the Quality Assurance Manager and Laboratory Director if work activity is suspended. The Quality Assurance Manager and/or Laboratory Director retain the authority to direct the Section Supervisor(s) to take additional action and/or document additional information as necessary.

On occasion, Laboratories will experience technical or administrative nonconformities. Such occurrences can compromise the quality of the work product and/or the integrity of evidence processed within the Laboratory setting. Nonconformities, as noted in the ASCLD/LAB-*International* Program Overview, can be defined as Level I or Level II, depending on the impact of the nonconformity on the Laboratory. The level of nonconformity will be considered in determining any course of corrective action. Nonconforming work shall be evaluated to determine its significance. Where this evaluation indicates the non-conforming work could recur or there is doubt about the compliance of the laboratory's operations with its own policies and procedures, corrective action will be initiated.

The severity of a nonconformance will be defined as follows:

4.9.1 Level 1 Nonconformities

The extent and impact of the discrepancy is severe. There is immediate and validated concern that

the quality of work being produced by an analyst/Section is poor and inconsistent with the Quality Management System. Level 1 nonconformities generally:

- are unexpected
- have a fundamental impact on the work product. Work product includes but is not limited to an analytical process, proficiency test, evidence integrity and/or quality policy and procedures.
- require an investigation to determine root cause
- require intensive corrective action
- Examples of this include a misidentification, a false identification, a false positive, failure to comply with quality policy and procedures, and/or compromised evidence.

4.9.2 Level 2 Nonconformities

The extent and impact of discrepancy does not affect the reliability of work or integrity of evidence within the laboratory. Level 2 nonconformities generally:

- have clear cut immediate cause
- can be addressed by simple actions (i.e., a note to file)
- are minor deviations from procedure which are addressed as part of routine business and can be addressed by simple actions.
- can be addressed and resolved in a timely fashion
- Examples of this include an administrative error, a facilities issue, a health and safety violation

4.9.3 Evaluation of a Nonconformity

When evaluating nonconformity, the lab shall refer to the Corrective Action (Section 4.11) for further instruction on how to pursue.

4.10 IMPROVEMENT

The MSPFSG continually looks for ways to continually improve the services it provides to its customers. This is done through management reviews, audits, corrective actions, preventive actions, and customer feedback.

4.10.1 Audits

The purpose of audits is to identify deficiencies or noncompliance at the earliest feasible point so that corrective action can be instituted. The ultimate goal should be to provide guidance, counseling, direction, and leadership in the effective and efficient management of resources and delivery on objectives of the MSPFSG. These audits include both internal and external audits.

The DNA Unit will comply with the audit cycle required by the FBI DNA Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories and the DNA Database Testing Laboratories.

4.10.1.1 Section/Unit Level Quality Audits (annual)

Quality Assurance Audits are one of the primary tools used to demonstrate that quality control procedures are being followed. Quality assurance must be flexible and adaptable to changes in both external and internal environments, i.e. new technologies, new developments in QAMS, new organizational needs and changing personnel situations. QAMS is responsible for conducting and scheduling quality audits of all laboratories annually in each functional area of the MSPFSG.

These audits are designed to assess compliance with quality standards other than those related to technical performance issues, which are reviewed as part of the Technical Audits (see below). QAMS will forward the audit report for review to the Section Managers and the Director. QAMS will maintain the audit records.

4.10.1.2 Technical Audits (annual)

Section Managers or designee will formally audit all MSPFSG Sections/Units and each satellite location annually. All efforts should be made to ensure that an interval of no less than six months and no more than eighteen months separate these annual audits. Managers will coordinate with the Section Supervisor to arrange a mutually acceptable date during which most section staff and the Section Supervisor will be present. At completion of the audit , the Section Manager will discuss what was observed with the Section/Unit Supervisor. The Section Manager will prepare a written report of the audit and forward to the Quality Assurance Manager.

The DNA technical audit will include a review of the quality manual, training manual, and procedures used by the laboratory and will be independent of the required FBI QA audit.

4.10.1.3 Compliance Audits (as needed)

Upon review of the Quality and Technical Audits, the Director may require a Compliance Audit to ensure that any significant negative findings are corrected. These Audits will be conducted by the Director or his/her designee. A report from this audit will be approved by the Section Manager and filed in QAMS with the original audit.

4.10.1.4 Safety Audits

Safety Audits will be conducted in accordance with the MSPFSG Safety Manual, but if practicable, should be undertaken in conjunction with the Quality Audits.

4.10.2 Internal Auditors

QAMS will ensure that internal audits are performed by qualified personnel. Documentation of audit training will be maintained in QAMS

4.10.3 ASCLD/LAB Annual Self Assessments

Each year, to meet the established timeline of ASCLD/LAB, the Quality Assurance Manager will meet with the Director and other Supervisors at the discretion of the Director. A review of ASCLD/LAB Accreditation Manual criteria and accreditation requirements will be conducted, and a

completed ASCLD/LAB self-assessment form will be forwarded to ASCLD/LAB for each laboratory by the Director.

4.10.4 Audit Record Retention
Audit reports and related documentation will be retained by QAMS for at least one accreditation cycle (5 years) plus one year. In addition to the audit documents, the following will also be retained for at least one accreditation cycle:

- Training Records
- Testimony Review Forms
- Calibration Certificates
- Sub-contractor audit documents
- Proficiency Test records
- Corrective Action reports
- Safety Audit Reports

4.10.5 DNA Quality System Review
The technical audit and the MSPFSG DNA Unit manual review complete the annual review of the DNA quality system

4.11 CORRECTIVE ACTION

4.11.1 Non-conforming work will be identified when any aspect of examination, calibration, or results does not conform to procedures or meet the agreed needs of the customer. This procedure applies to all work that impacts the accuracy of results and the integrity of evidence.

It is the responsibility of all employees of the MSPFSG to report observations of non-conforming work. It can be discovered through management reviews, technical and administrative reviews, audits, complaints, quality checks, or other means.

The Level of Non-conforming work is described in section 4.9

4.11.1.1 Any employee who identifies a potential Level I nonconformity shall inform their supervisor or a manager in their respective chain as soon as practicably possible, preferably before the end of the next business day.

4.11.1.2 The Supervisor shall briefly but clearly document the nonconformity, any immediate actions taken and its identification in an e-mail to their Section Manager, Deputy Director and Quality Assurance Manager within 2 business days of the identification. The Deputy Director and/or Section Manager, along with the Quality Assurance Manager, will notify the Laboratory Director within 1 business day of receiving the information.

4.11.1.3 The Quality Assurance Manager along with the Laboratory Director will determine if the non-conformity is Level I within one week of receipt of the e-mail, and if

so determined, will assign a team as well as designate a team leader to perform an investigation to determine the root cause(s).

4.11.1.4 The team shall include the Quality Manager or designee(s) and may include the Deputy Director and/or Section Manager(s).

4.11.1.5 QAMS will be notified of the team members and will assign a Corrective Action Report (CAR) number.

4.11.1.6 The team will confer with the Quality Assurance Manager or designee to develop an approach and establish a timeline for the investigation. Within 30 days of the investigation, a CAR will be developed by the team and Quality Assurance Unit, and provided to the Director for approval. The CAR will document the following items:

- The nonconformity and how it was identified
- The extent of the nonconformity
- The effect(s) of the nonconformity on the quality of work and/or integrity of evidence
- Any response to date

4.11.2 The root cause of the nonconformity will be determined by the team if possible.

4.11.3 The team will recommend a course of action and a schedule to correct the problem. This course of action will be a good faith effort to re-establish any analysts that have been removed from casework to address the non-conformities as well as minimize the disruption to laboratory operations.

Once the CAR is approved, the recommended course of action shall be implemented. Any changes required will be documented by QAMS.

4.11.4 Monitoring of Corrective Actions

4.11.4.1 If the course of action and/or follow-up activities extends over a protracted time period, the Section Manager, in consultation with the Quality Assurance Manager will generate regular progress reports to the Deputy Director, particularly on completion of milestones. The frequency of such reports should be defined in the CAR.

4.11.4.2 Upon completion of the course of action and/or follow-up activities, the Quality Assurance Manager along with the team will review the CAR and associated documentation, and make a written recommendation to the Director as to the status of the corrective action, and monitor the results to ensure the corrective action was effective. The Director will determine if the corrective action is complete or specify further action needed.

4.11.4.3 ~~The~~ QA ~~Unit~~MS will maintain all original CARs, reports, and recommendations for at least one full accreditation cycle. The Director shall have access to these records at all times.

4.11.5 Corrective Action Follow-up Audits

The Quality Assurance Manager and/or Laboratory Director will perform internal audits when necessary to ensure that the non-conformity is not indicative of staff/Sections failure to follow procedures. This will be defined in the CAR.

4.12 PREVENTIVE ACTION

4.12.1

All MSPFSG employees are responsible for monitoring work flow, technical procedures, and management system practices for potential improvements and/or potential sources of nonconformities. MSPFSG employees will follow this procedure for documenting, routing, implementing, and monitoring preventive actions. Employees should report their ideas and observations to management and report and take actions within their authority to prevent

nonconformities.

4.12.2
If an opportunity to improve the technical operations and/or management system or a potential source of nonconformity is identified, the following procedures will be followed:

- A written correspondence in the form of an email or memo will be submitted to the individual's supervisor. The Unit Supervisor and/or Section Supervisor will review and forward the form or email to the applicable Section Manager.
- The Section Manager will prepare and forward a brief written analysis of the recommendation to the appropriate Deputy Director as well as the Quality Assurance Manager and Director.
- The Director will assess the form and determine if action should be taken. If so, he/she will assign a team to address the preventive action. The team shall consist of the Quality Assurance Manager or designee, along with others assigned by the Director. During the formation of this team, a team leader shall be designated by the Director.
- The team will confer with appropriate staff to discuss possible actions. The team will then develop an approach and establish a timeline for implementation and then through the applicable supervisory chain, submit a written plan to the Director for approval.
- The team will oversee execution of the plan and will monitor and document its effect on the system.
- If the plan extends over a protracted time period, the team will prepare regular progress reports for the appropriate supervisors, Quality Assurance Manager, Deputy Director(s) and Director.
- Upon completion of the plan, the Team Leader in consultation with the team members will prepare and provide a summary report to the appropriate supervisors, Quality Assurance Manager, Deputy Director(s) and Director. The Director will either deem the preventive action completed or specify further action.
- The Quality Assurance Unit will maintain all original forms, plans and reports concerning preventive actions for at least one accreditation cycle. Team members will forward all appropriate supporting documentation to the Quality Assurance Unit. The Director may also maintain a copy of all forms, plans and reports pertaining to the actions taken within the system.

4.13 CONTROL OF RECORDS

4.13.1 General

4.13.1.1 Storage and Security of Records

All personnel are obligated to maintain the security and confidentiality of laboratory documents. Any observed breaches of security or confidentiality by any person must be brought to the attention of a Supervisor immediately. Supervisors will resolve the issue and inform the Section Manager, or designee of this resolution. The Section Manager or designee will determine the most appropriate

means of documenting the incident. Records are to be maintained in the most appropriate location for their use and accessed by a limited number of appropriate personnel. Any questions regarding the storage or use of a case file or other laboratory records must be forwarded for resolution to the appropriate Supervisor, Section Manager or to the Case Management Unit.

4.13.1.2 Accessibility
Records will be accessible to authorized personnel and properly stored and maintained to prevent any loss or damage.

4.13.1.3 Record Security
Records that contain confidential information must be maintained in a secure environment. The Laboratory Director is responsible for ensuring that files are secured properly. Quality Assurance records will be stored by the Quality Assurance Section under similar conditions.

4.13.1.4 Electronic Backup of Records
All electronic records must be stored in such a manner as to prevent unauthorized access, destruction, deterioration, or loss. The Massachusetts State Police ~~MIS~~OTIS(?) ~~Section~~ is responsible for backing up the network drives.

Section Managers are responsible for ensuring that the electronic records that are standalone in their respective Sections are backed up to prevent loss of information. Additionally, measures must be implemented to avoid loss or change of original data.

4.13.2 Shredding of Records and Documents

To keep the security and confidentiality of certain documents and records, any materials that need to be disposed of containing client names, case numbers, case information, or any real data involved in mock cases for moot court, must be shredded instead of merely discarded. In order to limit the disruptions affecting an analyst, certain sections may institute their own secured group collection bin which they are responsible to maintain. The collection bin will be a resting place for all documents to be shredded in the near future. This bin must be in a secured location where the general public does not have access. If more convenient, an analyst may have his/her own secured collection bin, but is held responsible for all things in the bin.

4.13.3 Disposition of Documents in the Completed File System

The disposition of documents is governed by MGL Chapter 30, Section 42 as amended. The application of this law is the responsibility of the Records Conservation Board (RCB) of the Commonwealth

4.13.4 Internal Disposition of Copies of Documents

Any copy of LIMS documents, any copy of case files, and/or copy of case data transposed onto another document must be shredded before being discarded. Each Section will maintain designated areas to collect documents to be shredded. The designated areas should be in a secured location inaccessible to the general public.

4.13.5 Case Records

Quality Assurance documents will be retained for one 5-year accreditation cycle plus one year.

4.13.5.1 Case Record Documentation

All administrative and technical documentation generated by the MSPFSG on a particular case constitute a case record. The case record contains and/or references all documents and data which are the basis for the conclusion of the laboratory reports. If no definitive conclusion can be reached (e.g. inconclusive), the reason must be clear in the case record. Additionally, if work is not performed or completed, or no report is issued, the reason(s) why must be documented in the case record, and the customer notified if necessary.

4.13.5.1.1 The following information must be contained in all case records and other technical data produced by the laboratory:

- All original case documentation in a case file will be denoted by a unique laboratory case number (LIMS number)
- This lab number and the analyst's handwritten initials (or secure electronic equivalent) will appear on each page of the case file (both sides if two-sided documents)
- Administrative documentation which is not generated in-house, such as a police report, and is bound together in some manner (e.g. stapled), may be identified with the laboratory number and initials on the first page only.
- If pages are added to a completed file, the pages must be secured and the initials/lab numbers and page numbers when applicable are the responsibility of the staff member who adds the documentation.
- Any changes made to completed examination records generated and/or maintained in an electronic form shall be tracked. Examination records are considered complete prior to any technical or administrative review.
- Corrections made to computer generated case file material will be made to the hard copy of the printed document rather than correcting it in the electronic file and reprinting it. Drafts of lab reports are exempt from this requirement.
- All case records will be stored in designated areas only.
- LIMS will reflect at ALL times the custody of a case file.
- All case documentation must support the conclusion such that, in the absence of the analyst, another competent analyst or supervisor can evaluate and interpret the data.
- Whenever appropriate, handwritten notes and observations will be permanent in nature by utilizing permanent ink and not pencil. Pencil (including color) may be appropriate if environmental conditions preclude the use of ink.
- All handwritten notes must be legible with any strikethroughs or corrections made by a single, initialed and dated strikeout.

- Any changes, alterations, or additional notations must be dated and intialeditialed by the person making the changes.
- ~~Any changes, alterations, or additional notations must be dated and initialed by the person making the change(s).~~
- The Examination start date and end date must be clearly noted in the case record. The start date will be the date the analyst first unseals any evidence and the end date will be the date the case record has been both technically and administratively reviewed, unless otherwise defined in Section/Unit procedures.
- A page numbering system may be required in specific Section/Unit procedures.
- Abbreviations and symbols may be used if the meaning of such is easily comprehensible to a reviewer, and their meaning is clearly documented in Section/Unit or MSPFSG procedures (unless a commonly acceptable abbreviation is used). Additional information may be required in individual Sections/Units as well, and will be specified in their procedures.

4.13.5.1.2 Administrative Documentation

Case record components include ALL administrative information stored in LIMS and should be referenced when necessary. It is not necessary to print this information out. Examples of this information include:

- Records of case-related conversations
- Documentation of "verbal" results provided
- Subpoenas and court testimony information
- Chain of custody information

4.13.5.1.3 Technical Documentation

Case records must include the following technical information:

- References to procedures followed
- Handwritten notes and/or forms and observations at the time they were made
- Chromatograms, spectra, and other instrumental data
- Sketches, diagrams, photos
- Reports
- Instrument Operating Parameters
- Reference to sampling plan(s) when applicable and relevant

4.13.5.2 Case Record Components

Case record components can be stored and maintained separately from the case file (e.g. batch standards, operating parameters). Section/Unit procedures must specify the location of such materials and the case record must reference this data.

When examination records are prepared by an individual(s) other than the analyst who interprets the findings, prepares the test report and/or testifies concerning the records, the handwritten initials (or secure electronic equivalent of initials or signature) of that individual(s) shall be on the page(s) of examination records representing his/her work.

The individual performing the work shall be marked clearly on all technical records and examination documentation within the case file. In cases where personnel write reports

Formatted: Font: 11.5 pt, Font color: Black, Highlight

Formatted: Indent: Left: 0", Hanging: 0.5"

Formatted: Font color: Black, Highlight

Formatted: Font: 11.5 pt, Font color: Black, Highlight

Formatted: Indent: Left: 0.5"

and/or testify based on examination document generated by another person (s), a review of all relevant pages of examination documentation in the case record is documented clearly. ~~If technical documentation performed by another analyst is included in the case file, the issuing analyst must initial each page of these examination records.~~

Verifications of critical findings and/or associations, such as a verification of a latent print identification, are considered part of the case record and must be documented. The documentation must clearly state what was checked, that there was an agreement, who performed the check, and the date it was performed.

The results from all tests performed must be documented in the case record. Section/Unit requirements for such reporting will be included in Section/Unit specific procedures.

Comment [I3]: These two additions are taken word for word from the ASCLD document and Boston PD QA manual. Not sure if that is allowed, so we might need to reword, but I think that its more specific then what was there and with what we had we would have to initial everything in case file every time. Not what I think the intent is.

Formatted: Font: 11.5 pt, Font color: Black, Highlight

Formatted: Indent: Left: 0"

4.14 INTERNAL AUDITS

The MSPFSG will conduct audits to verify that the operations being performed conform to agency policies in addition to ASCLD/LAB standards. (refer to 4.10.1)

4.15 MANAGEMENT REVIEWS

The MSPFSG will conduct a review of the management system.

4.15.1 MSPFSG Quality System Management Review

Management must conduct a review of the Laboratory's management system and casework activities at least once annually, in order to ensure that they continue to be effective, and to determine if there is a need for any changes or improvements to the system. This review will be performed by lab management and will be documented by QAMS. The documentation of the review will be retained for five years, or one accreditation cycle, whichever is longer.

The purpose of this review is to ensure that Management can continue to be confident that all measures are being taken to provide the highest quality service possible. The management system and laboratory actions must be evaluated to determine to their effectiveness and to identify any need for changes or improvements to the system.

The following will be reviewed annually:

- Laboratory policies and procedures
- Recent Internal Audit Reports
- Corrective and preventive actions
- Proficiency testing results
- Customer feedback
- Casework-volume, statistics
- Complaints
- Management reports
- Recommendations for improvement
- Other relevant factors.

Comment [I4]: Assessment by external bodies and Changes in volume and type of work are in the conformance file, but are not listed here specifically as the others are (other relevant factors is, so that may take care of it, but just letting you know that these are not specifically in here and they are in the requirements)

This review will be documented and any findings from the Quality System Management Review that require follow up actions will be carried out by appropriate personnel, as designated by the Laboratory Director, in a timely fashion. Documentation of follow up(s) will be forwarded to QAMS.

4.15.2 MSPFSG Quality System Policy and Procedures Review
All MSPFSG policies and procedures, including Technical Procedure Manuals, will be reviewed annually (at a minimum) by the Section Supervisor or designee. This review should ensure that the current policies are being followed, that any archived documents have been removed from circulation, and that any changes implemented have been properly documented. Documentation of this review will be forwarded to QAMS. (see also 4.3.9)

5. TECHNICAL PROCEDURES

5.1 General

The MSPFSG ensures accurate, reliable forensic examinations by using trained and competent personnel, appropriate facilities, validated analytical procedures, properly calibrated and maintained equipment, and by properly storing and control of evidence. When applicable, traceable reference standards and materials are used.

5.1.1 The laboratory will take into account factors that may affect the work done, including human factors, environment, validation of procedures, equipment/instrumentation, sample handling, evidence handling, and measurement traceability.

5.1.2 The reliability of reagents used in the laboratory will be verified.

5.1.2.1 All reagents must be labeled with the identity of the reagent and the lot number. Special storage and handling requirements and expiration dates should be noted if applicable. Records must be maintained identifying who made the reagent, and the results of any quality control checks (or performance checks) performed on the reagent. This may be accomplished in one of two ways:

5.1.2.1.1 Multiple Use Reagents (e.g. Duquenois Reagent)

- When batch stock reagents are made, all required entries will be made in an appropriate reagent log maintained in each Section/Unit.
- Each reagent log will record the name of the reagent, lot number (if assigned), initials of the person preparing the reagent, the date of preparation, and results of the reliability check.
- This must be recorded PRIOR to utilizing in casework.
- Each analyst is responsible for routine testing as required in the individual Section manuals.

5.1.2.1.2 Single Use Reagents (e.g. Sodium Rhodizonate)
When reagents are made for a single analysis only and then immediately disposed of, a reagent log does not need to be maintained, provided that the analyst's notes contain

- the identity of the reagent

- lot number and expiration date of chemicals used to make the reagent
- the results of the reagent performance check(s).

5.1.2.2 Controls and Standards
Testing performed at the MSPFSG is conducted using proper controls and standards that are compatible with the range of evidence examined and documented within the case records. It must be ensured that the reagents and materials are of the appropriate quality.

5.1.2.3 Unit Specific Requirements
Each Section will have specific requirements for testing of the reagents used, and will have procedure(s) that describe how to perform and document these checks, including acceptable limits, if applicable.

5.1.2.4 General Requirements
The following are general requirements which will be adhered to by all Sections:

5.1.2.4.1 All reagents, control samples, and standards, as well as chemicals and solvents which are received at the laboratory, must be labeled with the date on which they were received, and the initials of the person who received them.

5.1.2.4.2 Reagents used as received from the manufacturer will be assigned an expiration date of 10 years from date of receipt, unless otherwise dictated by the manufacturer or a specific Section/Unit policy. (e.g. DNA Unit-5 years)

5.1.2.4.3 Reference can be made to Unit Specific Quality Control procedures for relevant reagent testing. If the reliability testing of a reagent is not acceptable, then the reagent will be immediately removed from circulation. The Section/Unit Supervisor will be immediately notified, and a new reagent will be made and checked for reliability prior to any casework progresses utilizing this reagent.

5.1.2.4.4 The Section/Unit Supervisor will notify the Quality Assurance Manager if a corrective action is necessary due to a systemic issue with a reagent.

5.1.3 Standards/Control Samples

5.1.3.1 Standards and controls, whether made in-house , or purchased from commercial sources such as those used in the Drug Identification Unit, must be verified/tested prior to use. Verification will be done by performing appropriate analyses and comparing the results to published literature, in-house historical values, or other appropriate references.

5.1.3.2 In-house standards or controls (such as ethanol controls) must be tested against known standards and/or controls prior to use in casework. A file must be maintained with the test results of all standards/controls for future reference.

5.1.3.3 When available, reference materials which are traceable to National Institute of Standards and Technology (NIST) will be utilized. Certificates of Analysis must be kept on file when appropriate.

5.1.4 Internal Reference Materials

Reference collections of data or items encountered in casework that are maintained for identification, comparison, or interpretation purposes must be fully documented, uniquely identified, and properly controlled. These internal reference materials will be checked as far as is technically and economically practical, and according to Section/Unit specific requirements.

5.2 PERSONNEL

5.2.1 The MSPFSG has a responsibility to ensure all staff members receive proper training and follow a documented training program as applicable.

All employees of the Massachusetts State Police Forensic Services Group will have proper training and the educational background to perform their job duties. This training will include lab-wide training such as Health and Safety, as well as Section and Unit specific training.

Quality Assurance will maintain a quality assurance file (in hardcopy form and/or electronic) for each employee of the MSPFSG. Each employee and his/her supervisor will have unlimited access to their file. Documentation in this file will include: Curriculum Vitae/Educational Background, Statement of Qualifications, testimony review, proficiency test results, training and competency records, professional development/continuing education.

The Curriculum Vitae (CV) for each laboratory employee is available in their QA file located in the Quality Assurance Section. Each MSPFSG employee will forward a current CV annually as requested by QAMS and whenever significant changes (promotions, transfers, major training) occur. Additionally, all MSPFSG examiners who require proficiency testing will forward a statement of qualifications as needed. QAMS will notify employees when this information is needed.

Note: DNA analysts will have a transcript kept on file with the DNA Technical Leader. Training on statistics will be kept either by the Technical Leader or in QAMS.

5.2.1.1 Section Specific Technical Training will be developed by each Section Manager or designee. This training will include training for employees who are new to the Section, or who need remedial training or need to re-establish competency.

5.2.1.2 The Section/Unit training manuals must include discipline-specific topics, quality control, general knowledge of forensic science, and presentation of evidence in court (if applicable).

5.2.1.3 The Section/Unit training manuals must include training on the application of ethical practices in forensic sciences and applicable criminal and civil law and procedures.

5.2.2 Continuing Education and Professional Development
Training is provided to all employees as required at certain points in their professional developments. This includes training for new employees (e.g. MSPFSG-specific, safety, security, and technical training), training on new methods, or required annual training.

Note: DNA analysts must have a minimum 8 hours of DNA-related training annually. Please refer to the DNA training manual for specific requirements on course content and documentation requirements.

5.2.2.1 Administrative Training Programs
As developed, the Laboratory Director or designee disseminates these programs to all appropriate staff.

5.2.2.2 Laboratory Safety Training Programs
Introductory, periodic, and refresher training is provided. Additional training may be required to correct issues or reflect changing needs or technologies. Please refer to the MSPFSG Safety Manual for specific safety training requirements.

Annually, Section Managers will ensure that all staff members have read and are familiar with the ASCLD/LAB-International, ASCLD/LAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists (most current version). Documentation of this review will be forwarded to Quality Assurance.

5.2.2.3 Department of State Police Training Programs
As developed, the Laboratory Director or designee disseminates these programs to all appropriate staff.

All training programs should be reviewed annually as part of the manual review by the Section Manager, and the training program updated as necessary.

5.2.3 The laboratory uses personnel employed by the Department of State Police. If contract employees are used, the Section Supervisor will ensure they are supervised and competent and that records of training are forwarded to QAMS as appropriate

5.2.4 Job Duties
The Human Resources Department will maintain current job descriptions for all MSPFSG staff members, which include the general knowledge, skills, and abilities required for each position.

Note: More specific job descriptions are outlined for the following Sections/Units of the laboratory:
CSSS Job Descriptions (refer to QAMS-D006)
DEMS Job Descriptions (refer to QAMS-D005)
DNA Functional (refer to QAMS-D003)
FIS Job Descriptions (refer to QAMS-D004)

5.2.5 The Laboratory Director will authorize personnel to perform particular types of analytical testing, and

these authorizations will be on file in the Quality Assurance Office.

5.2.6 Educational Requirements

There are educational requirements for analysts working in certain disciplines in the Laboratory. Analysts who do not have the required degree may meet the educational requirements on a case-by-case basis as determined by ASCLD/LAB.

5.2.6.1 Educational Requirements

5.2.6.1.1 Analysts working in the Drug Identification Unit and the Trace Unit will have a minimum of a bachelor's degree in a natural science or closely related field.

5.2.6.1.2 Analysts working in the Toxicology Unit will have a minimum of a bachelor's degree in a natural science, toxicology, or closely related field.

5.2.6.1.3 Analysts working in the Biology Section will have a minimum of a bachelor's degree in a natural science, or closely related field. DNA analysts, CODIS Supervisor, and DNA Technical Leader will meet the educational requirements specified of the Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for DNA Databasing Laboratories.

5.2.6.1.4 Analysts working in the FIS, CSSS, DEMS, and Crime Scene Response will meet the educational requirements specified in their respective job descriptions.

5.2.6.1.5 Technicians working as technical support in any discipline shall meet the educational requirement(s) specified in the job description.

5.2.6.2 Competency Testing

5.2.6.2.1 Regardless of educational background or previous experience, each analyst must have completed adequate competency testing (internal or external) in all applicable areas of examination.

5.2.6.2.2 Competency testing should include evaluation of knowledge of existing literature, written and/or oral examinations, report writing, examination and identification of known and unknown materials, and testimony skill training. The specifics shall be included in the specific Section/Unit training manuals, and monitored by the Section Supervisor. Documentation of competency testing and compliance with the appropriate training manuals must be completed and forwarded to QAMS for inclusion in the employee's QA file, prior to performing independent work on evidence.

Upon successful completion of a/the competency test, the Section Manager or designee will issue a memo to the Laboratory Director indicating this completion, and requesting approval for this individual to begin analysis on case work. The Laboratory Director will provide written authorization to QAMS which will clearly specify the area of analysis the examiner is approved to perform. This authorization will be maintained in the examiner's QA file. A new authorization is required if new technology, instrumentation, or procedures are implemented.

5.2.6.2.3 Competency tests are necessary under the following circumstances:

- New employees must have established competency tests, which cover those areas of expertise needed to appropriately perform tasks on their casework.
- Employees returning to a Section/Unit after a period of greater than 12 months must have completed a documented competency demonstration program, tailored by the Section Manager to cover at a minimum those areas most likely to suffer from a loss of competence over time away from the work. (Note: Proficiency test performance during a period of absence from a Section/Unit may preclude the need for this requirement, at the discretion of the Section Manager, in consultation with the Quality Assurance Manager and the Director.)
- When new methods are implemented within a Section/Unit, as directed by the Section Manager or designee, in consultation with the Director and Quality Assurance Manager.
- When existing methods are updated with substantially different changes, within a Section, as directed by the Section Manager in consultation with the Director and Quality Assurance Manager.
- When remedial training is required due to an unanticipated Proficiency Test Result, an analytical discrepancy, or an unanticipated competency test outcome, at the discretion of the Director and in consultation with the Quality Manager.

5.2.6.2.4 Competency tests are designed and administered by the Section Manager or designee. These tests may be performed sequentially (i.e. one practical skill after another), or may be comprised of one master test that incorporates all required skills and abilities. The employee MUST complete competency test(s) prior to initiation of casework. For new employees, the competency test(s) must include the satisfactory completion of a documented training program in the assigned functional area.

The results of the completed competency tests are stored in the employee's QA files. The actual test may be stored in the Section or in central file storage if there is a LIMS number.

5.2.7 All staff assigned to MSPFSG must stay abreast of developments within their area(s) by reading current scientific literature and/or by attending seminars, courses, and professional meetings or documented training sessions/classes in relevant subject areas at least once per year. QAMS will maintain documentation of such continuing education. It is the responsibility of the staff to forward this documentation to QAMS.

5.3 ACCOMODATION AND ENVIRONMENTAL CONDITIONS

The design of MSPFSG facilities will maximize the functions and activities of the laboratory, while safeguarding the physical evidence and protecting the confidential nature of laboratory operations.

5.3.1 The laboratory must have adequate space and a proper design scheme to carry out its functions properly. The safety of all personnel and the integrity of evidentiary items are safeguarded by the physical structure and its components.

5.3.2 All laboratory working areas must have proper lighting, be equipped with proper plumbing and wiring, and be properly ventilated. Fume hoods will be available to remove noxious fumes. Proper and sufficient space is provided for storage of volatile, flammable, and hazardous materials.

5.3.3 Environmental conditions should not adversely affect the quality or validity of testing. The evidence storage conditions should be monitored, and the evidence properly stored from the time of acceptance into the MSPFSG until its proper disposal.

Employees are provided enough work space to efficiently accomplish their assigned duties without the risk of mishandling or contaminating evidence.

Each work area should have sufficient shelving, cabinets, drawers, or other storage space for proper storage and handling of individual and general laboratory supplies, equipment, and other tools necessary to carry out assigned tasks.

5.3.4 MSPFSG facilities will have space designated for the secure safekeeping of laboratory records and reports, as well as for reference materials, books, and other documents necessary for carrying out the function of the laboratory.

Please see the Massachusetts State Police Forensic Services Group Security Manual

5.3.5 Staff will utilize good housekeeping practices in the laboratory, following Unit specific procedures regarding cleaning work areas and decontamination, as well as those outlined in the Safety Manual.

5.3.6 Health and Safety

It is the responsibility of lab management to provide all personnel with a safe working environment, and for training staff in safe laboratory practices. The laboratory will have a designated Health and Safety Coordinator. Refer to MSPFSG Safety Manual for further information.

Please see the Massachusetts State Police Forensics Services Group Laboratory Safety Manual

5.4 Test Methods and Method Validation

All members of the MSPFSG shall use appropriate methods for performing testing. It is the responsibility of each analyst to follow the approved methods. Where appropriate, this includes measurement of uncertainty, calculations, statistical techniques, and procedural limitations.

Scientific methods and procedures employed by the MSPFSG should be generally accepted in the scientific field. However, they should not be construed as "standardized methods" that force a laboratory to use a single standardized technique to examine evidence, leaving little to the analyst's discretion.

5.4.1 Only approved technical procedures will be used in the analysis of casework. If a non-standard method is to be used, this method must be validated prior to use, and the customer must be informed of this deviation.

5.4.2 Technical Procedure Content

Section/Unit procedure manuals must describe the technical procedures used in the Section in a manner such that any examiner following the written procedure would perform the procedure in essentially the same manner, and would generate the same results. The procedure should include the following as applicable:

- Purpose, type of evidence to be examined
- Safety precautions
- Materials/supplies used
- Equipment used
- Quality control steps
- Controls and standards
- Evidence considerations
- Data, observations, and results to be recorded at the time they are observed
- Sampling procedures (if only a portion of item(s) is being tested)
- Conclusions
- Standard statements which specify the significance of the association or inconclusive results
- References
- Revision history
- Definitions/Abbreviations/Codes used

The equipment used during the procedure must have instructions on instrument use (either within the procedure or referenced elsewhere) if the absence of such instructions would jeopardize the results. The instructions must be readily available and will be considered controlled documents.

If there are environmental conditions that may affect the quality of results, these must be described in the appropriate procedure. This will include instruction on when testing shall be halted due to the possible compromise of the results of the examinations.

5.4.3

5.4.3.1 Each Section/Unit will have specific procedures on the maintenance, calibration, and use of all relevant equipment used.

Proper maintenance and calibration of instruments is essential for obtaining accurate and precise results. Instruments and equipment at the MSPFSG undergo calibrations, maintenance, and performance checks to ensure they are functioning appropriately, and documentation of these checks

must be maintained.

Each Section/Unit will have documented Quality Control procedures in place that are specific to the instruments used. All analytical instruments have periodic maintenance and/or are properly calibrated. The records of such are noted either in a logbook kept in close proximity to each instrument, or by another means defined in Section/Unit procedures.

Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled (or otherwise identified) to indicate the status of calibration, including the date when it was last calibrated and the date or expiration criteria for when recalibration is due.

If equipment, for whatever reason, goes outside the direct control of the laboratory, a performance check, however defined, must be completed prior to being put into service. This check must be documented.

New equipment will be checked (e.g. performance verification) before being placed into service to ensure it meets the necessary specifications established by the Section/Unit.

5.4.3.2 As appropriate, maintenance schedules for other specific instruments and equipment are outlined in Section/Unit manuals. Calibration certificates will be maintained by QAMS.

5.4.3.3 Certifications of critical measuring devices (e.g. balances, certain tape measures or measuring rods, micrometers) must be traceable to appropriate standards (e.g. NIST) when applicable.

5.4.3.4 An "Out of Service" sign or other similar notice will be placed on instruments/equipment that is/are broken or not currently in use.

5.4.3.5 Inventory
In accordance with the Department of State Police policy ADM-30, Asset Management, an inventory of all laboratory instruments and equipment will be kept. This provides laboratory management the necessary information for resource tracking and future allocation.

5.4.4 There may be instances when a deviation from an approved procedure is necessary These deviations are allowed with following provisions:

5.4.4.1 Requirements and Recommendations/Guidelines
Due to the variability in evidentiary samples and other circumstances encountered, many procedures are worded to include both recommendations (i.e. "should") as well as requirements (i.e. "shall" or "must").

5.4.4.1.1 Recommendations
An employee may deviate from a recommendation, however a notation explaining the deviation must be made in the case file or, if non-case related, in a relevant location. The employee must be able to discuss why this deviation is necessary.

5.4.4.1.2 Requirements

An employee may deviate from requirements with the following conditions:

- The employee will discuss the proposed deviation with his/her supervisor, with an explanation as to why it is needed, prior to implementing the deviation.
- If case circumstances warrant a deviation to procedure prior to supervisory approval, this must be documented in the case record and a Section Supervisor must approve as soon as practicable.
- The Supervisor will approve or deny the deviation based on the circumstances, consulting with the Technical Leader or Section Manager if necessary, to thoroughly evaluate.
- If approved, the deviation will be noted in the case file, or, if not case-work related, in a relevant location. This approval will include both the examiner and supervisor initials, along with the date approved in the case record. Electronic approval is acceptable if secured.

5.4.4.2 Standing Deviations from Procedure

Standing deviations may be documented in memo form, with a procedural change to be made according to the Document Control Procedure.

5.4.5 Validation

The laboratory must validate new technical procedures and/or methods prior to using on casework. This validation process includes the testing of known samples designed to resemble, as closely as possible, actual evidence materials. The process should take into account factors such as sample age, environment, sample homogeneity, and other factors as applicable. Current case samples cannot be used as part of a validation procedure.

5.4.5.1 Procedure for adding or updating a method

An analyst will issue an electronic memorandum to the Deputy Director, through channels, requesting a new/updated method. The Deputy Director will forward to the Laboratory Director, setting forth recommendations as to whether or not the development work should be done or the method incorporated into the system. The Laboratory Director may seek input from QAMS, however he/she will have final approval on whether to proceed with the valication. ~~The Laboratory Director may seek input from QAMS, however he/she will have final approval on whether to proceed with the validation.~~

Formatted: Indent: Left: 0.5", Hanging: 0.5"

Once the validation work has been completed, the Quality Assurance Manager will review the process to ensure compliance with the Laboratory's policies/procedures. QAMS will forward it along to the Director for final approval/disapproval.

5.4.5.2 Elements to include in validation

Where applicable, the initial validation process will include a validation plan that includes the following:

- the goals and objectives of the validation
- the expected cost of any supplies and reagents that will be needed, as well as additional

equipment that would be required
- study descriptions that include precision, sensitivity, etc.
- validation parameters for testing
- the types of samples to be used (i.e., purchased, simulated, previously disposed of evidence)
- the controls and standard reference materials to be used
- the method for evaluating the resulting data
- literature references
- draft procedure(s)

5.4.5.2 Validation Summary
Upon completion of the validation study, the results will be summarized for review, and the following information will be included if applicable:
- range and accuracy of values obtainable (this may include uncertainty of measurement, detection limit/sensitivity, selectivity/specificity, reproducibility, etc.)
- interference
- quality control measures that must be incorporated into the new method
- final draft of the technical procedure and any corresponding quality control procedures
- final cost/benefit analysis (which includes both technical and financial benefits and liabilities

5.4.5.3 Validation Review Process
The Section Manager (and the DNA Technical Leader where applicable) will review the validation and ensure that it is complete. Based on his/her review, the validation will be returned for further work or recommended for approval.

Once recommended, the Section Manager will forward the validation summary (and any applicable attachments) to the Laboratory Director for review and approval . It may be returned for further work or approved.

Once a validation is approved, the corresponding procedures will be implemented according to the Document Control procedure and Technical Procedure Content procedures.

5.4.5.4 Performance Checks
Often times, the MSPFSG will get new or additional instruments or software in which the technology has been previously validated and procedures are in place in the laboratory. Performance checks will be conducted on these instruments/software to ensure that a validated method works as expected. Performance checks may also be appropriate when minor modifications to the procedure or instrument/software are made. This will be at the discretion of the Section Manager (and DNA Technical Leader where applicable). The documentation will be kept on file with the instrument binder.

5.4.6 Estimation of Uncertainty of Measurement-refer to ASCLD/LAB Policy on this
The MSPFSG shall execute the following plan for coming into compliance with ASCLD/LAB-International estimated uncertainty of measurement requirements for measurements that matter.

5.4.6.1 The Deputy Director, Section Manager or designee, overseeing the Toxicology Unit, Drug Unit, Firearms Section and Office of Alcohol Testing, will be responsible for oversight and implementation of a plan to make their respective sections compliant with estimation of uncertainty requirements for accreditation.

5.4.6.2 The following measurements require uncertainty of measurement determination:

- blood alcohol concentration
- weights of controlled substances
- length of a firearm barrel
- Breath alcohol

5.4.6.3 The intended approach is to identify components of uncertainty and make reasonable estimations based upon those components using uncertainty budgets, certified reference standards (when applicable), historical data when suitable and available, and scientifically validated analytical procedures.

5.4.6.4 Each section required to complete uncertainty of measurement will provide quarterly updates to the Laboratory Director and Quality Assurance Manager for review, and have a documented plan for completion of the uncertainty of measurement determination and reporting.

5.4.7 Control of Data

5.4.7.1 All analysts are responsible for checking that calculations, data transcriptions, and data attachments are checked for accuracy prior to being submitted for technical review.

5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage, or retrieval of test or calibration data, the laboratory shall ensure that:

- Computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use. The validation must be approved by the Laboratory Director (and DNA Technical Leader when applicable) prior to use and documentation of the validation study will be on file in QAMS.
- Procedures are established and implemented for protecting the data, to include integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing.
- Computers and automated equipment are maintained to ensure they are functioning properly and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

5.5 EQUIPMENT

The MSPFSG has a responsibility to ensure that the laboratory has equipment/instrumentation that meets the needs of the technical requirements of the procedures.

Proper maintenance and calibration of equipment is essential for obtaining accurate and precise results. Instruments and equipment at the MSPFSG undergo calibrations, maintenance, and performance checks to

ensure they are functioning appropriately, and documentation of these checks must be maintained.

Each item of equipment and its software used for testing and calibration and significant to the result must, when practicable, be uniquely identified. Also, whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled orotherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

5.5.1 Procedures:

5.5.1.1 Each Section/Unit will have documented Quality Control procedures in place that are specific to the instruments used. All analytical instruments will have periodic maintenance and/or be properly calibrated. The records of such are noted either in a logbook kept in close proximity to each instrument, or by another means defined in Section/Unit procedures.

5.5.1.2 If equipment, for whatever reason, goes outside the direct control of the laboratory, a performance check, however defined, must be completed prior to being put into service. This check must be documented.

5.5.1.3 New equipment will be checked (e.g. performance verification) before being placed into service to ensure it meets the necessary specifications established by the Section/Unit.

5.5.1.4 As appropriate, maintenance schedules for other specific instruments and equipment are outlined in Section/Unit manuals. Calibration certificates will be maintained by QAMS.

5.5.1.5 Certifications of critical measuring devices (e.g. balances, certain tape measures or measuring rods, micrometers) must be traceable to appropriate standards (e.g. NIST) when applicable.

5.5.1.7 An "Out of Service" sign or other similar notice will be placed on instruments/equipment that is/are broken or not currently in use.

5.6 MEASUREMENT TRACEABILITY

5.6.1 All equipment used for tests and/or calibrations that have a significant effect on the accuracy or validity of the result of the test, calibration, or sampling shall be calibrated prior to being put into use.

5.6.2 A schedule will be established that outlines the calibration requirements for each piece of equipment.

5.6.3 Reference Standards and Reference Material

5.6.3.1 Reference standards must be calibrated before and after any adjustments are made. Each Unit will have a list of reference standards that need to be calibrated and they must be calibrated by a body that can provide traceability.

5.6.3.2 Reference materials will be traceable to certified reference materials. Internal reference materials shall be verified according to Unit specific procedures.

5.6.3.3 Each Unit will have its own procedures to ensure performance checks are conducted on reference standards and reference materials in such a manner as to ensure they are working properly and the expected results are being obtained.

5.6.3.4 As applicable, each Unit will have a procedure for the handling, storage, transport, and use of reference standards and materials to prevent contamination and deterioration and to protect their integrity.

5.7 SAMPLING

When reporting of results applies to an entire substance, material, or item(s), a sampling plan is required. Sample plans may include a representative sample of the whole or may be determined by availability of the item(s).

5.7.1 Each Section/Unit shall have a procedure outlined for the sampling of evidence, either within a specific procedure or as a whole. When reasonable, sampling plans shall be based on scientifically accepted statistical methods and must abide by applicable judicial requirements. The sampling plans shall address any factors that must be controlled to ensure valid examination results.

5.7.2 If the nature of the sampling requires a deviation from the sampling plan as outlined, then the analyst will document the deviation, and indicate on the report when appropriate. (Refer to 5.4.1 for deviations.)

5.7.3 Documentation of sampling data and activities relating to forensic examinations shall be recorded in the case file, including the sampling plan and statistical approach to the sampling if applicable.

5.8 HANDLING OF TEST AND CALIBRATION ITEMS

The MSPFSG is committed to the proper handling and storage of evidence to protect it from loss, contamination, and/or degradation, and to protect the evidence at all times.

The MSPFSG has developed procedures to ensure the integrity of all physical evidence that comes in to its possession. The laboratory uses submission forms in conjunction with a computerized chain of custody (LIMS). Evidence Submission procedures, along with instructions for the proper sealing, marking, and security of evidentiary items are addressed and described in the Evidence Control Section manual.

The Quality Assurance Manager and Section Manager must be notified of contamination events and loss of evidentiary samples.

Please see the Massachusetts State Police Forensic Services Group Evidence Handling and Submission Manual

Individual Sections/Units may have additional evidence handling requirements once an analyst opens and receives an item. These requirements will be described in more detail as required by each Section/Unit.

5.9 ASSURING THE QUALITY OF TEST AND CALIBRATION RESULTS

5.9.1 The MSPFSG shall have quality control procedures in place to monitor the validity of the results obtained. The data shall be recorded in such a way that trends are detectable. Quality Control measures include:

- reference collections
- routine use of certified reference standards
- participation in Proficiency Testing programs
- positive and negative controls
- spiked standards and internal controls
- verifications by other authorized personnel

5.9.2 Quality control data should be evaluated to ensure incorrect results are not reported.

5.9.3 Proficiency Testing

The MSPFSG is committed to providing the best quality service available to all members of the criminal justice community. While proficiency testing is an integral part of an effective quality assurance program, it is not the sole indicator of satisfactory performance. Proficiency testing can never replace the application of standards, controls, and other conventional quality assurance and control techniques.

5.9.3.1 Objectives

The objectives of the Proficiency Testing Program are to:

- Verify that technical procedures are valid and ensure that quality work is being maintained.
- Identify areas where additional training would be beneficial.
- Demonstrate the current competence of the laboratory.

5.9.3.2 Proficiency Test Requirements

Each analyst within the MSPFSG must complete at least one proficiency test annually (two annually for DNA) for each discipline (i.e. functional area) for which they generate reports. (Annually is defined as one per calendar year or as otherwise prescribed by standards mandated by the Federal Bureau of Investigation or other recognized standard-setting bodies.) A competency test may satisfy the proficiency test requirement for the year in which the competency test is successfully completed, at the discretion of the Section Manager and DNA Technical Leader, and in consultation with the Director and QAMS. Each analyst is required to complete one proficiency test for each category of testing in which he/she performs case work (e.g. fiber analysis within Trace Evidence) in each 5 year accreditation cycle. It is strongly recommended that they be done more frequently if resources permit.

Each year, every MSPFSG laboratory will complete at least one external proficiency test per discipline in which they provide service.

For the purpose of proficiency testing, crime scene processing activities by chemists are catalogued as a (multi-Section) sub-discipline.

5.9.3.3 Additional DNA Requirements

Each DNA examiner must participate in proficiency tests semi-annually from an ASCLD/LAB approved proficiency test provider. One test must be assigned in the first six months of the calendar

year and the second in the last six months of the calendar year. The interval between consecutive tests must be at least four months and not longer than eight months. For calculating time periods between tests, the assignment date will be used.

All analysts, technical reviewers, technicians, and other personnel designated by the DNA Technical Leader, must be externally proficiency tested semi-annually, in each DNA technology to the full extent in which they perform casework examinations. Technology is used to describe the type of forensic DNA analysis performed in the laboratory (e.g. STR, Y-STR). It is permissible for multiple technologies to be reported on a single proficiency test. However, all individuals must be tested semi-annually in each technology performed to the full extent in which they participate in casework.

If an analyst is qualified in both manual and automated methods for DNA extraction, then the analyst must be proficiency tested in each method at least once per year to the full extent in which he/she participates in casework. If multiple manual and/or automated methods are available, the analyst must be proficiency tested on at least one of the manual methods and one of the automated methods per year. This does not preclude the possibility that both methods may be administered on a single proficiency test.

If an analyst is qualified in multiple quantitation kits (e.g. Quantifiler and Quantifiler Y), then the analyst must be proficiency tested in each method at least once per year to the full extent to which she participates in casework. This does not preclude the possibility that both methods may be administered on a single proficiency test.

If an analyst is qualified in both manual and automated methods for DNA interpretation, e.g. GeneMapper ID™ and TrueAllele Databank™, then the analyst must be proficiency tested on each method in each test to the full extent in which he/she participates in casework. This does not preclude the possibility that both methods may be administered on a single proficiency test.

Within the calendar year, interpreting DNA analysts/non-interpreting DNA analysts/ DNA technicians and technical reviewers must perform each stage of DNA analysis on proficiency samples that s/he utilizes when doing casework.

5.9.3.4 Proficiency Test Program Administration

The Proficiency Testing Program is managed under the direction of the MSPFSG Quality Assurance Manager. The Quality Assurance Manager or his/her designee is responsible for:

- Procuring tests
- Scheduling assignments with Section Supervisors
- Assigning and Distributing tests in a timely fashion
- Providing input to Supervisors during review/evaluations of test results
- Maintaining a database to track all proficiency testing information
- Communicating with laboratory staff regarding test results

Assistance in sample preparation may come from each Section Manager, Supervisors or other personnel as required.

Each year, QAMS will prepare a draft proficiency testing schedule in consultation with the Section Managers.

5.9.3.5 Proficiency Test Providers

5.9.3.5.1 External
ASCLD/LAB Proficiency Review Committee approved proficiency test providers will be utilized as required by ASCLD/LAB in procuring external proficiency tests. Refer to the ASCLD/LAB website for the most up to date information on approved providers.

5.9.3.5.2 Internal
There may be times when an external proficiency test is not available or practical. In these instances, internal PTs may consist of previously expired PTs if appropriate or internally prepared PT's.

When using expired PT's, the samples will be repackaged in such a manner that any association with the original manufacturer test number will be precluded.

When prepared in house, it must be done in consultation with the Section Supervisor using the following guidelines:

- The composition of the test will be determined based on the type of procedures used and the samples tested.
- The test should use samples and methods that ensure integrity, uniformity, and identity of the sample.
- Test scenarios and expectations must be explained to the analyst prior to beginning the test, and this information, including answer key, will be retained in QAMS.
- Duplicate samples should be prepared and retained if possible, or the samples should be prepared in such a way that retesting can be done if necessary.
- If the PT is a comparison, the test should be produced in a fashion which allows for meaningful analysis and comparison, and have sufficient class/individual characteristics.
- Controls should be included as necessary.

5.9.3.6 Proficiency Test Responsibilities
To the greatest extent practicable, or unless otherwise mandated by external quality assurance standards, proficiency tests shall be completed exactly in the way casework is done including evidence handling, analysis, and all normal technical and administrative reviews. Any deviations from this must be approved by the Quality Assurance Manager.

The test results will not be discussed with other staff members unless required for technical or administrative review.

It will be the responsibility of QAMS to ensure that appropriate proficiency test samples are

assigned and provided to each analyst far enough in advance to facilitate completion by the analyst prior to expiration of the annual accreditation due date. It is the responsibility of the Section Supervisors to notify QAMS who requires proficiency tests so that they are assigned appropriately. The Quality Assurance Manager or designee will then enter the appropriate assignment and due dates into the database and notify the analyst of this assignment.

If a proficiency test cannot be completed by the due date, the analyst will provide a memorandum through channels to their Deputy Director with the reason(s) for such. The Deputy will forward the memorandum to the Quality Assurance Manager before the due date. The record of the request for an extension of the due date must be entered into the case file. The Quality Assurance Manager must approve this extension, providing a new due date, and documenting appropriately in the Proficiency Test database and case file.

Upon completion of the proficiency test, the analyst will fill in the required entries on the Proficiency Testing Program Cover Sheet, attach it to the case file and/or proficiency test documentation and submit it to their respective supervisor. Proficiency test samples will be returned to the Evidence Control Section following normal chain of custody procedures. The analyst must make appropriate entries in LIMS for the case file.

The Supervisor reviews the file, initials the proficiency cover sheet, enters the transfer in LIMS and forwards the file to the QAMS.

The proficiency test samples will be returned to the Evidence Section upon completion. These samples will be retained for one ASCLD/LAB accreditation cycle of 5 years.

5.9.3.7 Proficiency Test Reviews

QAMS will forward the proficiency test documentation with results from the supplier, as soon as they become available, to a competent staff member for grading. The grader is an individual assigned by QAMS in consultation with the appropriate Section Supervisor and/or Manager to aid in the evaluation of proficiency test results. The proficiency test grader must be a qualified technical reviewer in the applicable discipline.

If the analyst's results are consistent with the vendor results and what the lab expects, the grader will inform QAMS of the result, by completing the appropriate section of the Testing Program Cover Sheet. QAMS will forward this information to the analyst and the Section Supervisor for notification. The analyst may sign/date the notification and return to QA for storage with the PT file.

Notifications may be done electronically, provided that adequate documentation is maintained to show that this notification was received by the analyst.

Any test that does not yield consistent results will be forwarded to the Deputy Director and in consultation with QAMS, there will be a detailed review and cause analysis.

5.9.3.8 Proficiency Test Completion

Following completion of all actions, all documentation will be forwarded to and stored by the QAMS. The following documentation will be maintained for each test completed:

1. Unique Identifier
2. Identity of Test Provider (external) or information on the test preparation (internal)
3. Analyst
4. Date of analysis
5. Date of Completion
6. All data, worksheet, notes and other information used to support conclusions
7. Report of results
8. Any discrepancies noted
9. If external, the provider's proficiency test evaluation
10. Any corrective action documentation, if applicable, including PRC inquiries and any other applicable correspondence
11. Documentation of any notifications to analyst and/or staff

5.9.4/~~5.9.5~~ Case File Review

Case file review is an important part of the Quality Management System and it is the responsibility of the analyst to construct, organize, and produce a quality work product prior to forwarding for review. Review ensures that all issued laboratory reports and results utilize accurate forensic analyses.

Procedures are in place to ensure that conclusions and reports released from the laboratory are reasonable and within the constraints of scientific knowledge. This is accomplished by employing review procedures and ensuring that specific criteria are met.

- All case files in which a laboratory report is generated must undergo technical and administrative review.
- There are two types of review performed on case files: Technical and Administrative.
- It is important to note that the review process does not shift the responsibility for an analyst's findings to the reviewer. Each analyst has the ultimate responsibility for their casework and any report(s) issued. The reviewer is responsible to ensure that the documentation does reflect adequate basis for any conclusion(s) however.

5.9.4 Technical Review

A technical review is a review which evaluates the report as well as bench notes, data, and other documents which form the basis for scientific conclusion.

5.9.4.1 ALL results issued from the MSPFSG will undergo technical review.

5.9.4.2 Individuals performing such review must have expertise in a specific functional area which has been gained through documented training and experience. This includes reviewing policies and procedures and other documents as applicable in each Section to effectively evaluate the case files. If the expertise for such a review is not found within the laboratory, the Deputy Director and QAMS will seek assistance from a qualified reviewer outside the laboratory and this reviewer's qualifications will be kept on file in the QA office. Approval from the Laboratory Director is needed to authorize this

reviewer.

5.9.4.3 Each individual performing technical review must have authorization from the Laboratory Director to perform such reviews, and this authorization must be on file in QAMS.

QAMS will maintain a current list of personnel qualified to perform the technical reviews, and the Section Supervisors will forward any changes to the lists as they occur.

5.9.4.4 Staff members shall NOT perform technical review on their own case files. If they have performed batch analysis, or analysis on any item(s) that will be part of someone else's case file, then that work MUST be technically reviewed by another analyst and this review must be documented.

Staff members may not review their own assignments in LIMS. If this information is stored electronically in LIMS it must accurately reflect who performed the review.

5.9.4.5 Process

5.9.4.5.1 Though each Section may have discipline specific requirements, at a minimum, the following will be verified during this review:

- Compliance with all applicable sections of the Section's procedures
- Accuracy of the report and that all reported results and/or conclusions are supported by data in the case record
- Any associations are properly qualified in the report
- The report contains all the information required by the Section's procedures

5.9.4.5.2 Discrepancies Identified in Technical Review

If there is a discrepancy identified during the review process, the reviewer will bring it to the attention of the analyst for resolution. If the discrepancy is not resolved, it will be brought to the Section Supervisor, who will further evaluate and resolve. The following steps will be taken until resolution is achieved:

- An individual who is experienced and performs technical review in that discipline, either external or internal to the laboratory, will be consulted. This must be a mutually agreed upon individual by the analyst and the Section Supervisor, as well as reviewer
- If there is still no resolution after such as consultation, then the Quality Assurance Manager and Section Manager will decide whether reanalysis or other suitable action is needed
- Under no circumstances will an analyst be forced to sign an analytical report containing opinions or conclusions with which they disagree

5.9.5 Administrative Review

An Administrative review is a review of a case record to ensure that the information is consistent with laboratory administrative policies, as well as for editorial correctness.

5.9.5.1 All analytical results issued from the MSPFSG will undergo Administrative review, and this review will be documented, according to each Section's specific requirements for review.

5.9.5.2 Administrative Review will be performed by staff members who have been provided with specific training by the Section, in accordance with written standards for the review.

5.9.5.3 Each individual performing an administrative review must have authorization from the Laboratory Director to perform such reviews, and this authorization must be on file in QAMS.

QAMS will maintain a current list of personnel qualified to perform the administrative reviews, and the Section Supervisors will forward any changes to the lists as they occur.

5.9.5.4 Staff members MAY NOT perform administrative review on case files in which they author the report.

Staff members may not review their own assignments in LIMS. If this information is stored electronically in LIMS it must accurately reflect who performed the review.

5.9.5.5 Process

5.9.5.5.1 Though each Section may have discipline specific requirements, at a minimum, the following will be verified during this review:

- Spelling and grammatical accuracy
- Review of the case file to ensure that pages are labeled appropriately with the laboratory number and initials of appropriate staff
- Ensure all strikethroughs and carets are initialed and dated
- Ensure that the test report contains all key information

5.9.5.5.2 Any discrepancies identified through the administrative review process will be brought to the attention of the analyst and/or technical reviewer for resolution. If substantive changes are made that require another technical review, the dates of further technical review will be documented, with a note to file if necessary.

If the discrepancy cannot be resolved, the administrative reviewer and analyst will consult with the Section Supervisor and Quality Assurance Manager to determine a

solution.

5.9.6 Verbal Results

It may be necessary to provide verbal results prior to issuing a completed laboratory report. Please refer to Section-specific procedures if this occurs.

5.9.7 Testimony Review

Court testimony can be evaluated by several mechanisms. At least annually, a Testimony Review Form will be used to record the testimony of each analyst who testifies. It is strongly recommended that this review be conducted by a supervisor/peer. If not available, then it may be performed by an authority of the court (e.g. a judge or an attorney).

After review, the peer or supervisor will discuss the assessment with the analyst to provide feedback on the testimony. Any technical deficiencies that are discovered through testimony review must be brought to the attention of the Section Supervisor for corrective action as appropriate.

The analyst and supervisor will review and initial the testimony review form and attach comments if warranted. The analyst will then attach the completed form in Activity Log in LIMS.

Each time an analyst is to testify, the analyst must notify his/her supervisor who will assess the case and arrange testimony review if appropriate.

Testimony Review forms will be kept on file in the Quality Assurance Office for 5 years, or one accreditation cycle.

Note: The QA Section will maintain documentation of those analysts who do not testify each year

5.10 Reporting the Results

5.10.1 The MSPFSG has an obligation to accurately, clearly, explicitly, and objectively report the summary of findings. This includes conclusions and/or opinions drawn from any analysis and observations.

Report writing is a critical aspect of the analyst's work at the MSPFSG. The conclusion rendered must be justified by the nature and the amount of evidence that is presented for examination. Reports must be supported by valid data, must be easy to read, and grammatically correct. Results obtained must be conveyed in a clear, concise, and accurate manner to the recipient.

When a laboratory does not produce a report on analytical work that is conducted, clear information must be available in the case record file as to why no report is being issued or why work was ceased.

5.10.2 Each Section may have specific requirements that will be included in reports issued from the Section,

but the MSPFSG has standard information that is to be included. If this information is not available in the report it must be contained in the case record.

5.10.2.1 The following information is required when examinations and/or analysis have been performed:

- Title
- Lab Number or Case Identifier
- Date of Report
- Name and address of the laboratory
- Agency information including the appropriate victim/suspect name, agency case number, investigating officer, and address of the customer
- Identification of the method used
- Date of receipt of the test items when critical to the validity of the result and the dates of performance of the test.
- Reference to any sampling procedure(s) followed
- Description of evidence examined
- Results of examinations, and, when applicable, a statement that the results relate only to the items tested
- A signature and title, or equivalent identification, of the person accepting responsibility for the content of the report.
- Each page of the report must be numbered (page 1 of xx) and marked with the laboratory number.

Note: Each Section may have additional reporting requirements specified by Section procedures. DNA reports will include information required by the FBI Quality Assurance Standards.

5.10.3 Case Records

In addition to information listed in 5.10.2, the case record will include, when necessary for interpretation of the test results, the following information: The methods followed, deviations if applicable, uncertainty of measurement, and other information which the customer requests.

When associations are made, the significance of the association must be clearly communicated and qualified properly.

5.10.4 Calibration Certificates

5.10.4.1 In addition to the requirements listed in 5.10.2, the calibration certificates shall include the following, when necessary for the interpretation of the results, or they must be available in the case record:

- any environmental conditions that may have an effect on the results
- uncertainty of measurement
- evidence that the measurements are traceable

5.10.4.2 Refer to 5.4.6.4

5.10.4.3 When an instrument for calibration has been adjusted or repaired, the calibration results

before and after the adjustment/repair will be reported.
5.10.4.4 The calibration certificate will be issued with a one year calibration requirement.

5.10.5 The following , or a similar statement with this information, will be noted on each report issued from the laboratory:

"This report reflects the test results, conclusions, interpretations and/or the findings of the analyst as indicated by the signature below" above the signature of the analyst.

5.10.6 When a report contains results from tests that are performed by subcontractors, these results will be clearly identified as such.

5.10.7 Laboratory results and reports may be issued by hardcopy, electronically or verbally. If provided electronically or verbally, documentation of who this information is provided too, the date it is provided, exactly what was provided, and the means of transmission must be noted in the case record.

5.10.8 Reports issued from the MSPFSG shall be on Department of State Police letterhead.
Note: Prima Facie Certification, Test of Blood Under G.L. Ch. 90, Sect. 24 (1)(f)(2) reports are excluded from this requirement.

5.10.9 Additional Report Types
Corrected and/or supplemental reports may be issued on a case file, and this will be clearly marked on the report.

5.10.9.1 Supplemental Reports
Supplemental Reports are generated when additional examinations or analysis are performed. These must clearly be identified as "Supplemental Reports" and will list additional evidence received and its description, if not stated in the previous report. If more than one Supplemental report is generated, a numbering system must be used to clearly distinguish reports (i.e. Supplemental 1, Supplemental 2, etc.)

5.10.9.2 Corrected Reports
Corrected reports will be generated if a report has been issued from the laboratory and corrections are necessary. This applies to administrative changes as well as technical changes. They must be clearly identified as "Corrected Reports" and clearly indicate the correction(s) being made. If more than one Corrected Report is generated, a numbering system must be used to clearly distinguish reports (i.e. Corrected Report 1, Corrected Report 2, etc.)

The need to issue a corrected report may indicate a failure in the review process. Therefore, the Quality Assurance Manager will receive notification from the analyst or supervisor if a corrected report is being issued, and why. The Quality Assurance Manager will track potential issues and determine if corrective or preventive action is needed.

5.10.10 Dissemination of Laboratory Reports

A copy of each signed laboratory report must be maintained with the case record. The original signed report will be issued to the investigator (or the Prosecutor, depending on the circumstances).

6.0 REVISION HISTORY

Version	Issue Date	Revisions By	Total Pages	Revision
1.0	12/1/2012	QAMS	61	Original-combine all QA Manuals
2.0	DRAFT	QAMS		MinorAdministrative, section 5.2.6.1.2 changed to Toxicology, addition of ASCLD/Lab Guiding Principles reading.

Formatted Table

ALL SIGNATURES ON FILE IN QUALITY ASSURANCE

7.0 MANUAL REVIEW

_____ _____

Quality Assurance Manager Date

8.0 AUTHORIZATION

_____ _____

Laboratory Director Date

_____ _____

Deputy Division Commander of Forensic Services Group Date